LEVEL 1®

OPERATOR'S MANUAL

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Level 1® H-1200
Fast Flow Fluid Warmer

With:
H-31, Version B,
Air Detector/Clamp

REF H-1200 115V

REF H-1200 230V

Rx ONLY

CE 0473

smiths medical

LEVEL 1®

Level 1® H-1200 Fast Flow Fluid Warmer

With:
H-31, Version B, Air Detector/Clamp

REF H-1200 115 V

REF H-1200 230 V

OPERATOR'S MANUAL

P/N 40-6917-51A

smiths medical

General Information

Level 1® H-1200 Fast Flow Fluid Warmer

Part Number: 40-6917-51A

This revision supercedes all previous revisions.

Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company, however, reserves the right to improve the equipment shown.

Mention of third-party products is for informational purposes only and constitutes neither an endorsement nor a recommendation. Smiths Medical assumes no responsibility with regard to the performance or use of these products.

For further information, please call your local Smiths Medical distributor or Smiths Medical direct at 1 800 258 5361 or +1 614 210 7300.

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SECTION 1

About this Manual

WARNING: These instructions contain important information for safe use of the product. Read the entire operator's manual, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

This Operator's Manual describes the set-up, use, and maintenance of:

- Level 1® H-1200 Fast Flow Fluid Warmer
- Level 1® H-1000 Fast Flow Fluid Warmer with H-2 Pressure Chambers (H-1025)
- Level 1® H-1000 Fast Flow Fluid Warmer with H-2 Pressure Chambers and H-31, Version B, Air Detector/Clamp

The manual is intended for use by individuals trained in the healthcare and biomedical professions.

This operator's manual is also for users of the H-1000 Fast Flow Fluid Warmer. All references to the "Level 1® H-1200 Fast Flow Fluid Warmer" apply to the H-1000 Fast Flow Fluid Warmer except where indicated by the symbols defined in the following table.

Symbol	Description
H-1200	Appears in the margin to identify information that only applies to the H-1200 Fluid Warmer and the H-1000 Fluid Warmer equipped with the H-31, Version B, Air Detector/Clamp
H-1000	Appears in the margin to identify information that only applies to the H-1000 Fluid Warmer (not equipped with the H-31, Version B, Air Detector/Clamp)

Conventions Used in this Manual

This manual uses the following text and text conventions:

Convention	Description
CONTRAINDICATION	A Contraindication statement alerts the user to conditions when the device should not be used.
WARNING	A Warning statement alerts the user to conditions that may cause death or serious injury to the patient or user.
CAUTION	A Caution statement alerts the user to conditions that may cause malfunction, failure, or damage to the device.

This manual is organized into the following sections:

2 and 3 Description and Indications for Use
These sections provide the purpose and indications for use of the Level 1® H-1200 Fast Flow Fluid Warmer.

4 Important Safety Information
Lists the Contraindications, Warnings, and Cautions associated with the use of the Level 1® H-1200 Fast Flow Fluid Warmer.

5 Out of the Box—Assembly
Guides the user through the installation of the Level 1® H-1200 Fast Flow Fluid Warmer and the Level 1® H-31, Version B, Air Detector/Clamp.

6 Principle of Operation
Provides a functional description of the Level 1® H-1200 Fast Flow Fluid Warmer.

7 Controls and Displays
Provides a description of the function and purpose of the controls, displays, and indicators for the Level 1® H-1200 Fast Flow Fluid Warmer.

8 Operation
Describes Operation, Indicator, and Alarm modes of the Level 1® H-1200 Fast Flow Fluid Warmer.

9 Operating Instructions
Describes the Set Up, Use, and Alarm modes of the Level 1® H-1200 Fast Flow Fluid Warmer.

10 Troubleshooting
Contains information on troubleshooting the Level 1® H-1200 Fast Flow Fluid Warmer. This section also details troubleshooting slow fluid flow rates.

11 Testing
Describes Operational, Performance, and Electrical Tests that are used to verify the proper operation of the Level 1® H-1200 Fast Flow Fluid Warmer.

12 Maintenance
Regular maintenance procedures for every use, 30-day, and 12-month intervals are covered in this section.

13 Limited Warranty
Describes the Limited Warranty and its provisions.

14 Service
Explains Non-Warranty Work as well as listing Service Contacts.

15 Specifications
Provides physical, environmental, and electrical specifications of the Level 1® H-1200 Fast Flow Fluid Warmer.

16 Symbols
Lists the symbols and their definitions used with the Level 1® H-1200 Fast Flow Fluid Warmer.

SECTION 2

Description

The Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) is an I.V. fluid warmer with pressure chambers, air detection, and automatic clamping capability. I.V. fluid and/or blood products are warmed through the use of a sealed heat exchanger through which a recirculating solution flows. Pressure Chambers apply pressurization and deliver the fluids at a fast flow rate. This non-invasive method employs single-use, disposable administration sets that include a Gas Vent/Filter Assembly and Heat Exchanger.

H-1200

The Air Detector/Clamp monitors for the presence of air in the disposable Gas Vent/Filter Assembly. When air is detected in the Gas Vent/Filter Assembly, the Air Detector/Clamp closes off the patient line and alerts operators to the presence of air with audible and visual alarms. An ultrasonic signal continually passes through the fluid filled Gas Vent/Filter Assembly. As a bolus of air displaces the fluid in the Gas Vent/Filter Assembly, the ultrasonic signal is broken and the clamp closes, stopping the air before it enters the patient line. Audible and visual alarms are activated, notifying the user that the fluid flow has stopped. Clearing the bolus of air and restoring the fluid flow are quickly accomplished without disconnecting from the patient.

Disposable Administration Sets

The installation, set up, and replacement of Level 1® Fast Flow I.V. Disposable Administration Sets (Disposable Sets) follows a four-step sequence that corresponds to numbered blocks on the device. Disposable Sets available for use on the Level 1® H-1200 Fast Flow Fluid Warmer are listed below.

- DI-50
- D-60 / DI-60HL
- D-70 / DI-70
- D-100 / DI-100
- D-300 / DI-300

D-series Disposable Sets are for use in the U.S.A. DI-series Disposable Sets are for use in markets outside of the U.S.A.

SECTION 3

Indications for Use

The Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) provides a rapid flow of warmed fluids, such as crystalloid or blood product, including red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.

The Fluid Warmer provides fast flow of warmed fluid to re-warm patients during surgery by trained medical personnel.

SECTION 4

Important Safety Information

This section covers information for prescribers and guidelines for safe use of the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer).

CONTRAINDICATIONS

Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions.

WARNINGS

Death or serious injury may occur to the patient or user if these warnings are not followed:

- **These instructions contain important information for safe use of the product. Read the entire operator's manual, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient or user.**
- **Remove all air from the fluid bags before spiking and the fluid lines before connecting to the patient. Failure to do so can result in infusion of air into the patient.**
- **Replace Gas Vent/Filter Assembly every three hours, or when the filter becomes clogged, or when air is slowly vented. Failure to do so will result in a reduction of flow rate. This may result in inadequate patient treatment**
- **The replacement Gas Vent/Filter Assembly must be fully primed before continuing infusion. Failure to do so may allow air to be infused into the patient.**
- **Do not use the Fluid Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The Fluid Warmer may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.**
- **Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution and I.V. fluid path, resulting in the I.V. delivery of inappropriate fluids.**

WARNINGS *[continued]*

- **Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens.**

- **When injecting medications into the fluid path, do not inject through the triple lumen tubing of the D/DI-60HL Disposable Set. This may allow communication between the recirculating solution and I.V. fluid path.**

- **Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if MAINS power cord has exposed wires.**

- **Do not re-use partially full fluid bags. Fluid bags that have been partially drained, un-spiked, and then reinstalled may contain air, which if used can result in infusion of air into the patient. Use only new fluid bags from which the air has been removed.**

- **Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in death or serious injury to the patient.**

- **The Fluid Warmer is not for use with irrigating tubing, which may not fit into the clamp slot of the Air Detector/Clamp causing diminished flow or a failure to stop flow.**

- **The Fluid Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and D or DI series Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets.**

- **Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.**

- **Use of a bedside leukocyte reduction filter may cause a sudden precipitous drop in blood pressure resulting in respiratory distress, facial flushing, abdominal pain and nausea, and loss of consciousness. Immediately stop transfusion, and follow institution's protocol for treatment of transfusion reactions.**

- **Do not operate the Fluid Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of**

WARNINGS *[continued]*

explosion exists if the Fluid Warmer is operated in a potentially explosive environment.

- No user-serviceable parts. All service must be performed by Smiths Medical or competent personnel.
- Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Set if Luer and spike caps are not securely in place, or if Luer connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.
- Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets.
- If fluid exits the Patient Line of the D/DI-60HL Disposable Set, replace the Disposable Set.
- Do not use auto-transfusion bags. Auto-transfusion bags may contain air that can result in infusion of air into the patient.
- Set-up, priming, and use require aseptic technique. Failure to use aseptic technique may result in death or serious injury to the patient.
- Do not use the Fluid Warmer if equipment or Disposable Set malfunction is evident.
- No modification of this equipment is allowed.

WARNINGS for the Air Detector/Clamp

H-1200

- The tubing must be properly placed in the Clamp Slot of the Air Detector/Clamp. Failure to ensure that the tubing is correctly positioned in the Clamp Slot may result in failure to stop air infusion.
- Activation of the Air Detector/Clamp alarm during infusion indicates that fluid flow has stopped and that immediate operator intervention is required to restore fluid flow. Failure to reinstate flow (after purging any air or foam) may result in death or serious injury to the patient.
- Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the patient line to be delivered to the patient resulting in serious injury or death.

WARNINGS for the Air Detector/Clamp *[continued]*

- **The functional test for the Air Detector/Clamp accessory must be performed before each use. If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Fully functional visual and audible alarm systems are essential for the safe use of the Air Detector/Clamp.**

CAUTIONS

Malfunction, failure, or damage to the device may occur if these cautions are not followed:

- **Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the Fluid Warmer.**
- **Do not place the Fluid Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the Fluid Warmer or into the external connectors.**
- **When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur.**
- **Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.**
- **Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.**

SECTION 5

Out of the Box—Assembly

This device must be assembled and tested by authorized Smiths Medical personnel, an authorized distributor of Smiths Medical, or competent personnel prior to placing the device into service.

The following steps describe how to assemble and do preliminary set up of the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer).

Refer to Step 8 if you need to install the Level 1® H-31, Version B, Air Detector/Clamp to the Level 1® H-1000 Fast Flow Fluid Warmer.

Step 1	Verify components of the Fluid Warmer	
Step 2	Assemble I.V. Pole to Warming Unit	
Step 3	Install Pressure Chambers	
Step 4	Attach the I.V. Bag Hanger	
Step 5	Disinfect the Recirculating Solution Reservoir	
Step 6	Preliminary Preparation	
Step 7	Connect the Pneumatic Tubing	
Step 8	Install the Level 1® H-31, Version B, Air Detector/Clamp	H-1000
Step 9	Perform Electrical Safety Tests	

Read through the instructions completely prior to setting up the device.

Note: *After unpacking the system, recycle packaging material according to hospital policy for recyclable materials.*

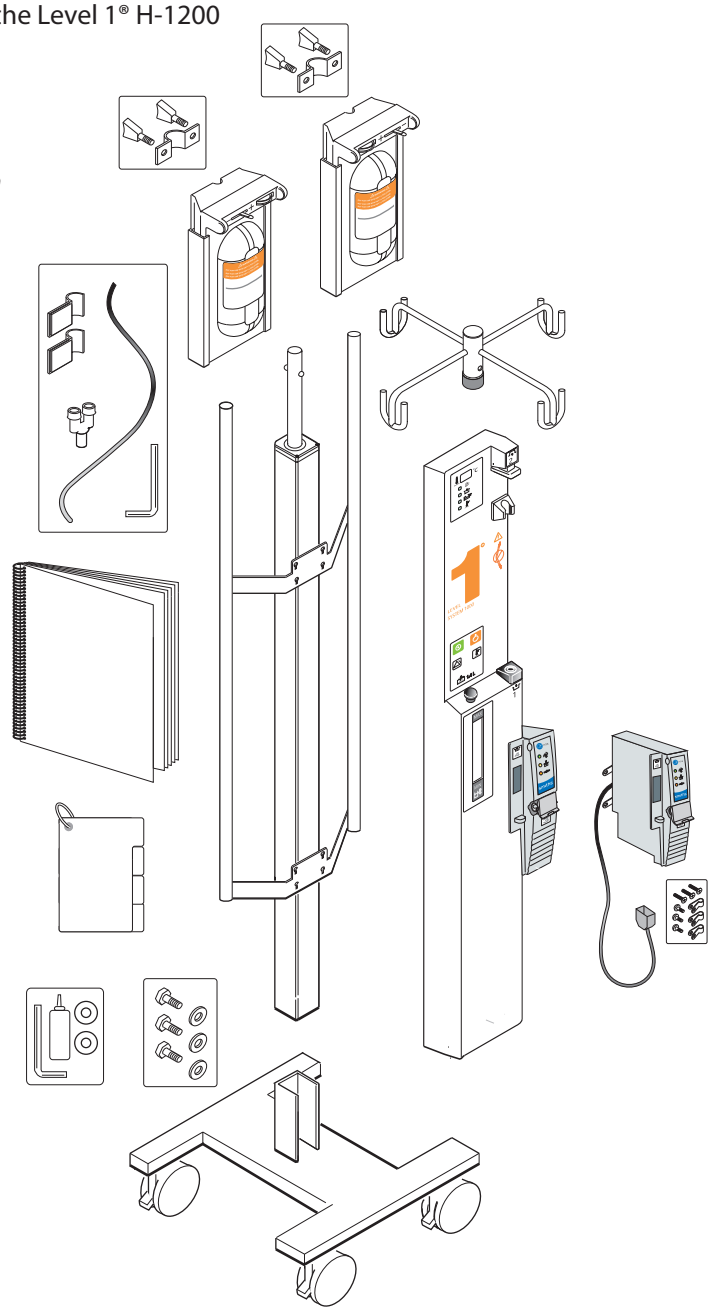
Step 1 – Verify Components of the Level 1® H-1200 Fast Flow Fluid Warmer

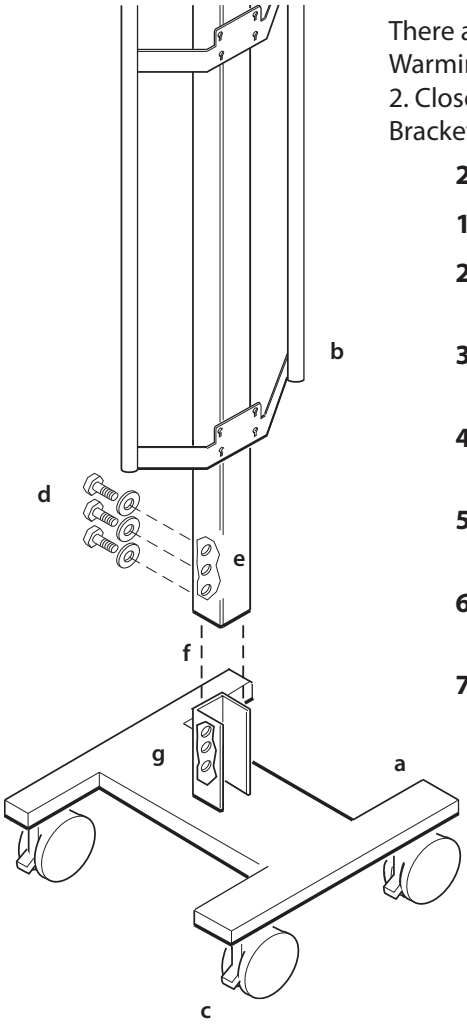
Note: *The Level 1® H-31, Version B, Air Detector/Clamp is shipped as a separate accessory only for installation on an existing Level 1® H-1000 Fast Flow Fluid Warmer.*

Check the contents of all packaging to verify that the following components are present. If any parts are missing or damaged, do not use the Fluid Warmer. Do not substitute parts not supplied by Smiths Medical. Contact Smiths Medical for replacement parts. Below is a listing of the component parts for the Level 1® H-1200 Fast Flow Fluid Warmer.

Components Checklist

Qty	Component
	in order of appearance in illustration
2	Pressure Chambers / Contents: (2) "U" brackets (4) Thumbscrews
1	I.V. Bag Hanger
1	Fluid Warming Unit
1	**H-31, Version B, Air Detector/Clamp**
1	**Accessory Pack** **(3) Pan-head screws** **(3) Power Cord Clips** **(3) Flat-head screws**
1	Operator's Manual
1	Quick Reference Guide
1	I.V. Pole with Flanking Brackets
1	Accessory Pack / Contents: (2) Plastic "J" Clamps (1) Y Connector (1) Black Tubing (1) Hex Wrench
1	O-Ring Kit / Contents: (1) Silicone (2) O-Rings (1) Hex Wrench (1) Instructions for Use
3	Bolts
3	Washers
1	I.V. Pole Base





Step 2 – Assemble I.V. Pole to the Warming Unit

There are three steps involved in assembling the I.V. Pole to the Warming Unit. The steps are: 1. Assemble the I.V. Pole to the Base, 2. Close the Drain Valve, and 3. Attach the Warming Unit to the Flanking Brackets. Each step is detailed in a short procedure.

2.1 Assemble the I.V. Pole to the Base

1 Locate the I.V. Pole Base **(a)**.

2 Locate the dark-gray extruded I.V. Pole **(b)** with Flanking Brackets.

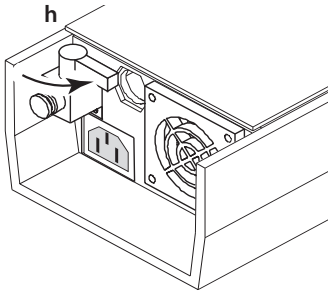
3 Place the I.V. Pole Base upright on its wheels, **(c)** and lock the wheels to prevent movement during set up.

4 Locate three bolts **(d)** and washers for the pole base.

5 Align the three holes **(e)** in the I.V. Pole with the three screw holes on the pole base.

6 Slide the I.V. Pole down over the pole base, **(f)** keeping holes aligned.

7 Guide three bolts and washers through the holes **(g)** at the base of the pole and tighten.



2.2 Close the Drain Valve

Turn valve, located on the bottom of the device, perpendicular to stem **(h)** of the Warming as shown.

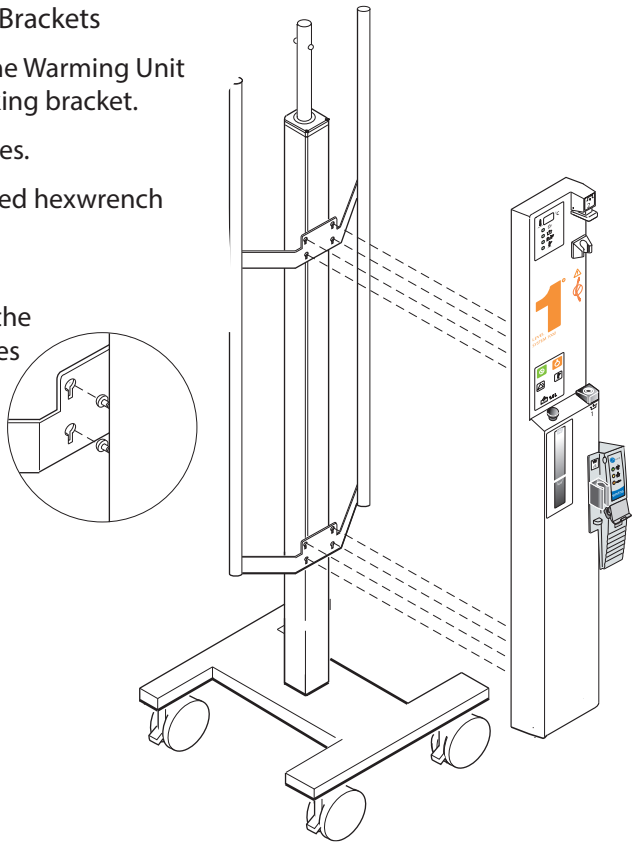
2.3 Attach the Warming Unit to the Flanking Brackets

1 Align the eight hex screws on the back of the Warming Unit with the eight keyhole notches on the flanking bracket.

2 Slide screw heads down into keyhole notches.

3 Tighten all eight hex screws with the supplied hexwrench and secure in place.

2.4 Attach the Quick Reference Guide to the Fluid Warmer by sliding the ring on the Quick Reference Guide over one of the poles on the Flanking Bracket.



Step 3 – Install the Pressure Chambers

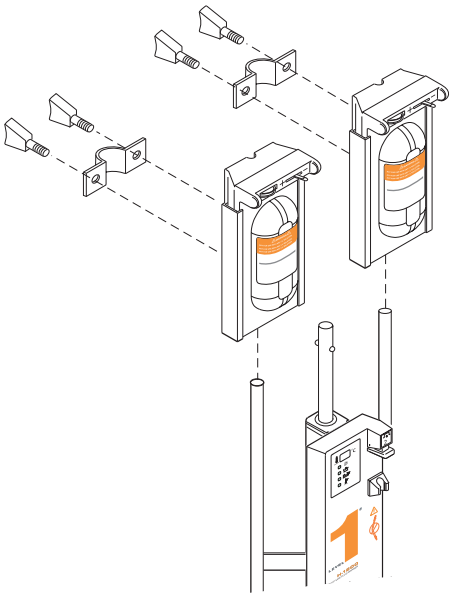
1 Locate the two Pressure Chambers.

2 Locate the U-brackets and thumbscrews supplied with the Pressure Chambers.

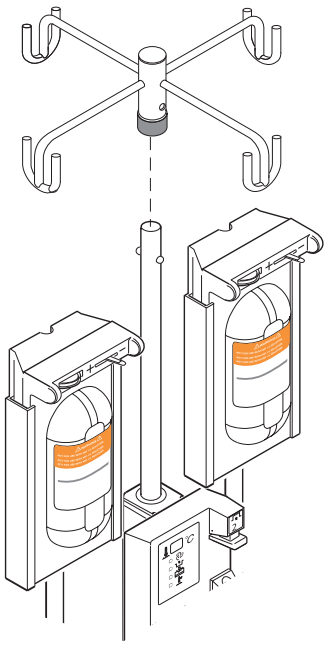
3 Attach the U-brackets with thumbscrews to the back of the Pressure Chambers, as shown. Keep thumbscrews and brackets loose.

4 Slide one Pressure Chamber with attached U-bracket over the top of each flanking pole.

5 Align the U-bracket slightly below the top of the flanking pole. Tighten the thumbscrews securely.



Step 4 – Attach the I.V. Bag Hanger



1. Slide the I.V. Bag Hanger on top of the I.V. Pole.
2. Align with tabs.
3. Press down and snap into place.

Step 5 – Disinfect the Recirculating Solution Reservoir

1. Remove the fill-port plug (a) on the reservoir.
2. Prepare a 0.3% hydrogen peroxide/distilled water solution for the reservoir. Mix 140 ml of 3% hydrogen peroxide solution and 1,260 ml of distilled water.
3. Fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide/distilled water solution.
4. Replace the fill-port plug.
5. Insert a Disposable Set into the Fluid Warmer.
6. Insert the power cord into a properly grounded receptacle.
7. Turn the Fluid Warmer ON. Let the solution circulate for a 30-minute disinfection period.
8. Turn the Fluid Warmer OFF.
9. Empty the reservoir.
10. Remove the Disposable Set and discard according to established hospital procedures.

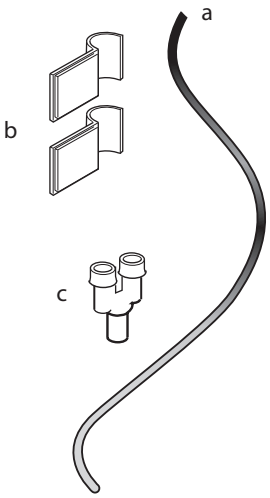
Step 6 – Preliminary Preparation

1. Remove the fill-port plug **(a)** on the front of the warming unit and fill the reservoir to the maximum level with 1.4 liters of one of the following solutions:
   - 0.3% Hydrogen Peroxide/Distilled Water Solution
     Mix 140 ml of 3% hydrogen peroxide and 1,260 ml of distilled water.

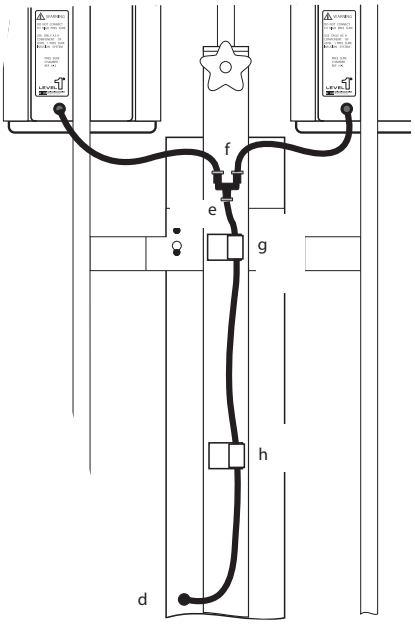
     Note: *If this option is selected, the maintenance requirement to change the recirculating solution is once every 12 months. Always use a 0.3% hydrogen peroxide/distilled water solution when refilling the reservoir.*
   - Distilled Water

     Note: *If this option is selected, the maintenance requirement to change the recirculating solution is once every 30 days.*
2. Replace the fill port plug.
3. Lubricate O-Rings in #1 Block **(b)** and #2 Block **(c)**. Place a small amount of silicone lubricant, provided in the supplied O-Ring Kit, on a cotton swab and apply all around the inside of each O-Ring.

Step 7 – Connect the Pneumatic Tubing



1. Locate the Accessory Pack with the black pneumatic tubing (a), two "J" clamps (b), and one "Y" Connector (c).



2 Locate the orange protective plug in the red ring connector (d) located on the back of the device. Remove the plug by depressing the red plastic ring as you pull the plug out of the connector.

3 Take the pneumatic tubing and press one end of the tubing firmly into the ring connector **(d)** until it can go no further.

4 Take the "Y" connector and press the other end of the pneumatic tubing into the bottom of the "Y" connector, as shown **(e)**, until it can go no further.

5 Press the pneumatic tubing from the Pressure Chamber into place **(f)** on the top of the "Y" connector until it can go no further. Repeat this procedure with the pneumatic tubing from the other Pressure Chamber.

6 Remove the protective backing sheet on one "J" clamp, exposing the adhesive side.

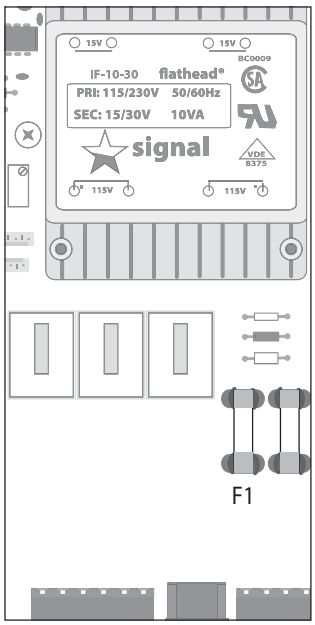
7 Carefully position the "J" clamp and press the adhesive side against the gray I.V. Pole in the approximate locations **(g)(h)** shown.

Press down firmly to secure in place.

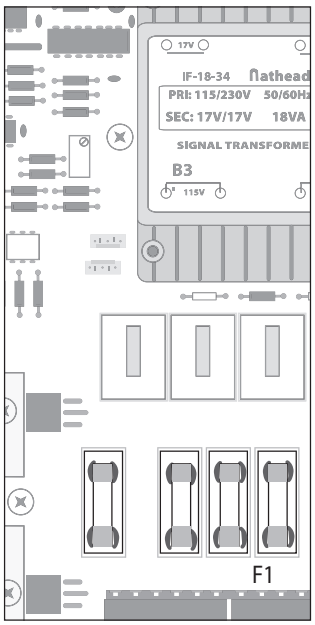
Repeat this procedure for the other "J" clamp.

8 Press the pneumatic tubing into place on the "J" clamps.

Step 8 – Install the Level 1® H-31, Version B, Air-Detector/Clamp



Two Fuse Configuration



Four Fuse Configuration

Before installing the Air detector, determine if the Fluid Warmer was manufactured before 2004. If it is, inspect the "F1" fuse to confirm that it is the correct value and type. The year of manufacture can be determined by the serial number label which is located on the bottom right side of the unit, or for older units on the inside. If the first four characters of the serial number are numbers, then the numbers represent the year of manufacture (e.g. 20040100 would be manufactured in 2004). If the first character of the serial number is the letter "J", then the year of manufacture is prior to 2004 (the letter "S" indicates the year 2007 or later). For units manufactured prior to 2004, perform the following.

1 Disconnect the power.

2 Remove the 18 screws from the rear of the Fluid Warmer and remove the back panel.

3 Locate the "F1" fuse on the electronic assembly. See figures to locate the "F1" fuse for either a two fuse configuration or a four fuse configuration.

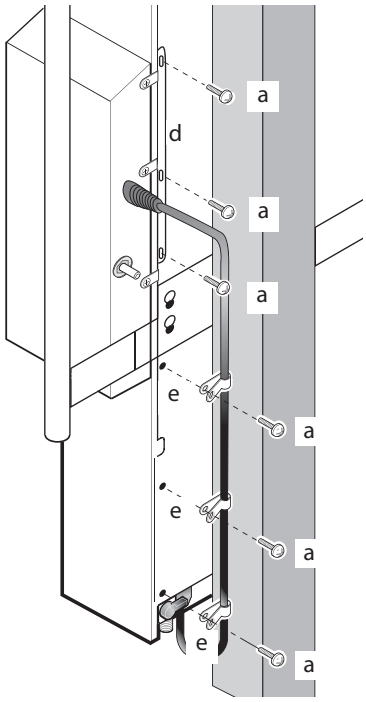
- For 100 - 120V Fluid Warmers,

  Remove the fuse and verify that T6.3AL250V (time lag, 6.3 amp, 250V fuse), is printed on one of the silver end caps, if not replace the fuse with a new fuse marked T6.3AL250V.

- For 220 - 240V Fluid Warmers,

  Remove the fuse and verify that T3.15AL250V (time lag, 3.15 amp, 250V fuse), is printed on one of the silver end caps, if not replace the fuse with a new fuse marked T3.15AL250V.

4 Replace the back panel and insert all but 6 of the screws (**a**) as indicated in Step 1 below. Then proceed to install the Air Detector/Clamp.

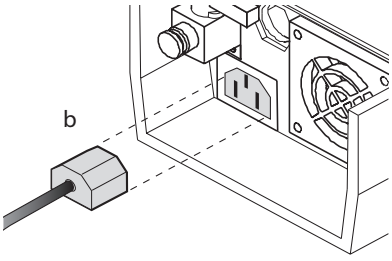


To install the Air Detector/Clamp,

1 Remove 6 screws (**a**) from the rear of the Fluid Warmer, lower left side, from locations shown in figure.

2 Plug in the power cord (**b**) of the Level 1® H-31, Version B, Air Detector/Clamp into the auxiliary MAINS outlet located on the bottom of the Fluid Warmer.

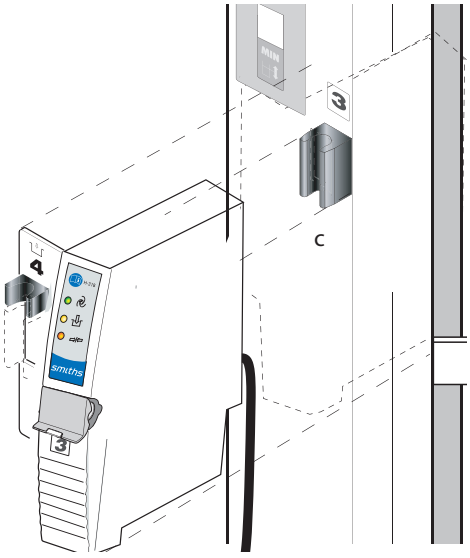
Note: *If you turn the Fluid Warmer off and the Air Detector/Clamp does not turn off, contact Smiths Medical or your local Smiths Medical distributor.*



3 Loosen the three screws holding the mounting bracket to the rear of the Air Detector/Clamp (do not remove).

4 Align the slot on the Air Detector/Clamp with #3 Block on the Fluid Warmer (**c**). Fit in place over the block.

Note: *Do not bend the mounting bracket while holding the Air Detector/Clamp against the fluid Warmer.*



5 Carefully align the mounting bracket on the rear of the Air Detector/Clamp with three screw holes, shown (**d**). Ensure that the gasket seal on the Air Detector/Clamp is flush with the Fluid Warmer. Insert three flat-head screws and tighten, securing the Air Detector/Clamp to the Fluid Warmer. Tighten the three screws on the mounting bracket on the Air Detector/Clamp.

6 Locate three power cord clips (**e**) included with the Air Detector/Clamp and snap onto power cord. Align clips with the three screw holes as shown, insert screws, and tighten.

7 Install and prime a Level 1® Fast Flow I.V. Disposable Administration Set, and test the audible and visual alarms and Air Detection/Clamp as described in Section 9 *Operating Instructions*.

Step 9 – Perform Electrical Safety Tests

Perform all applicable electrical safety tests as required per institutional procedure. These include but are not limited to:

- Leakage current
- Hypot
- Ground bond test

WARNING

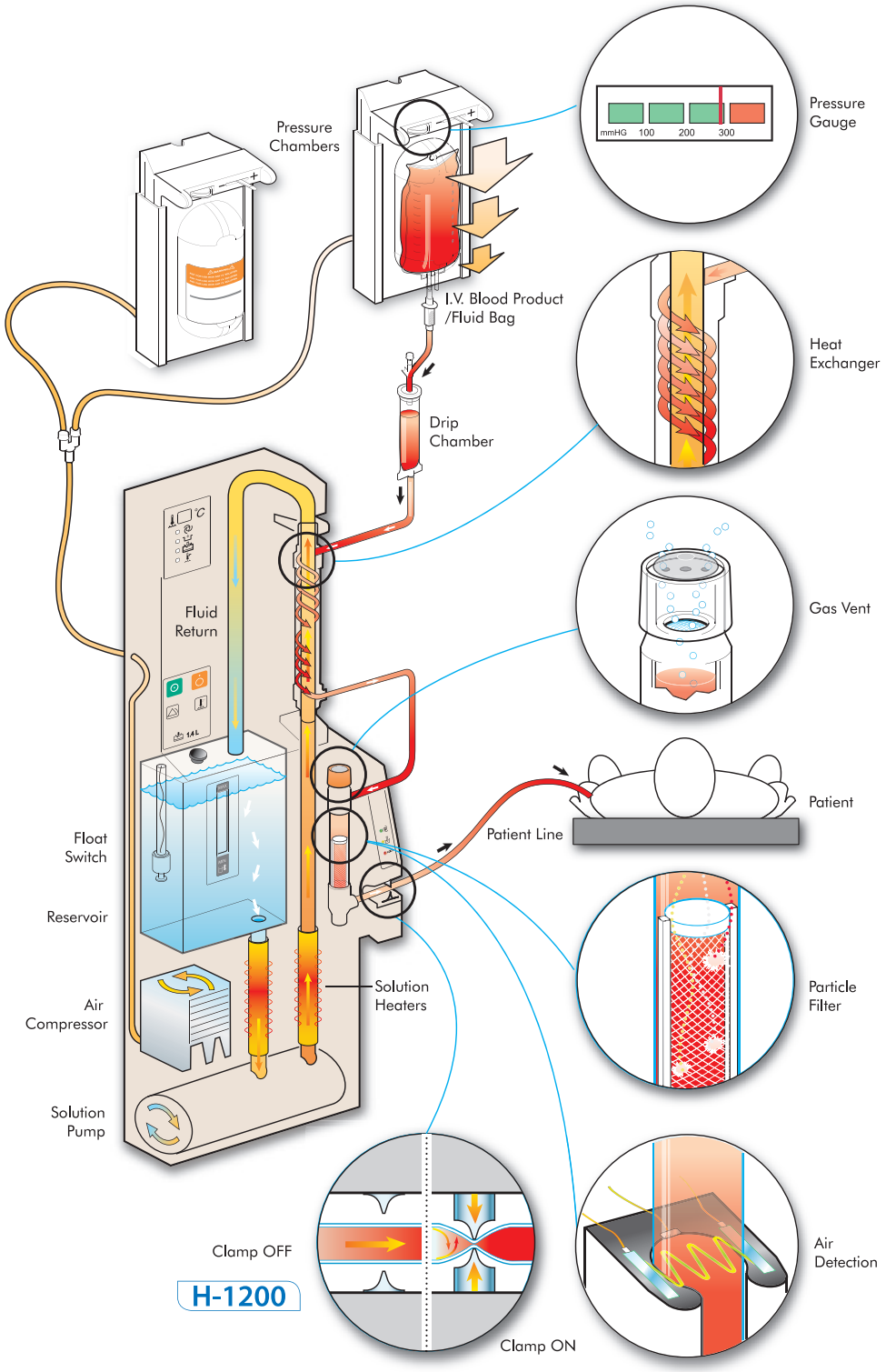
Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle resulting in death or serious injury to the patient or user.

The Electrical Safety Check must be performed by competent personnel authorized by the institution to perform such testing. The Safety Check must be performed and documented at least once per year, or according to institutional policy.

H-1200

Fast Flow Fluid Warmer

Principle of Operation Schematic



SECTION 6

Principles of Operation

The schematic illustration on the facing page depicts the Level 1® H-1200 Fast Flow Fluid Warmer's (Fluid Warmer) operations. The primary operations are described below.

Fluid Warming

The Fluid Warmer utilizes a solution reservoir housed in a controller unit. Recirculating solution is warmed and pumped through a heat exchanger (a part of the Disposable Set). The solution is returned to the reservoir for continuous recirculation and remains isolated from the patient and from the I.V. fluid path. The on-board recirculating solution is heated to a pre-set manufacturer's temperature set-point. The system continuously monitors and controls the recirculating solution temperature. The Fluid Warmer is designed to shut down and provide audible and visual alarms in the event of an over-temperature condition.

Pressurized Fluid Delivery

The Fluid Warmer provides pressurized fluid delivery through the use of an on-board compressor and two Pressure Chambers. The Pressure Chambers pressurize the fluid bags for fast fluid delivery.

Air Detection/Clamping

H-1200

The Air Detector/Clamp detects the presence of air in the Gas Vent/Filter Assembly — a part of the Level 1® D/DI series Disposable Administration Sets (Disposable Sets) — and clamps the patient line. An ultrasonic signal continually passes through the fluid-filled Gas Vent/Filter Assembly. As a bolus of air displaces the fluid in the Gas Vent/Filter Assembly, the ultrasonic signal is broken and the clamp closes, stopping the air before it enters the patient line. Audible and visual alarms are activated, notifying the user that air has been detected and fluid flow has been clamped off. Clearing the bolus of air and restoring the fluid flow are quickly accomplished without disconnecting from the patient.

SECTION 7

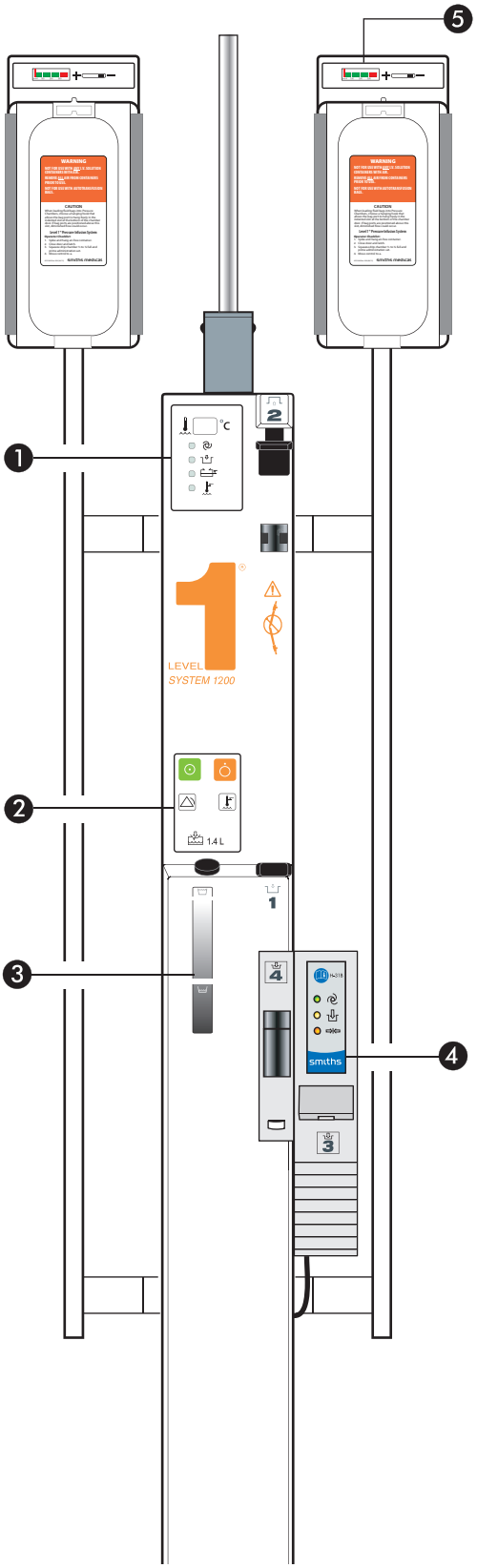
Controls and Displays

Five locations on the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) govern how the device is controlled and where function indicators are displayed. They are called-out in the figure and are defined in the list below.

H-1200

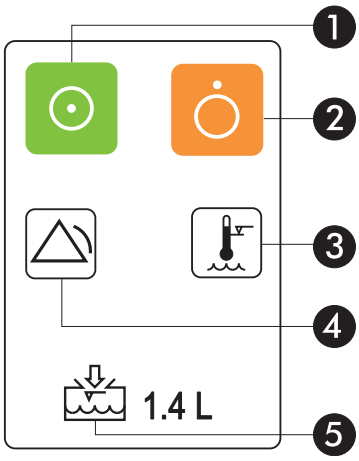
1. Fluid Warmer Display Panel
2. Power and Alarm Test Panel
3. Reservoir Level Display
4. Air Detector/Clamp Control Panel
5. Pressure Chamber Control Panel

The Fluid Warmer has five Interlocks, which detect for correct installation of a Disposable Set, that are also defined this section.



Fluid Warmer Power and Alarm Test Panel

The Power and Alarm Test Panel is located on the front of the Fluid Warmer directly above the reservoir fill-cap. This panel contains four pressure-sensitive buttons that are activated when pressed. Refer to the Power Alarm Test Panel below whose numbered call outs correspond to a description of the button and the function it performs.



Button/Function

1 **Power ON Button**
The green button on the top-left of the Power and Alarm Test Panel powers on the device. Power is applied to the on-board compressor for the pressure chambers and the Air Detector/ Clamp. The green Automatic Operation LED on the Fluid Warmer Display Panel illuminates when the Power ON button is activated, with a Disposable Set in place.

2 **Power OFF Button**
The Power OFF is the orange button to the right of the Power ON button on the Power and Alarm Test Panel. This button turns power off to the unit. The green Automatic Operation LED on the Display Panel will turn off when this button is pressed.

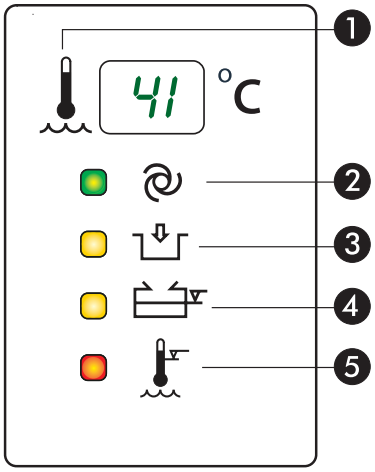
3 **Over Temperature Test Button**
The Over Temperature Test is used to confirm the proper operation of the Over Temperature circuitry. Testing the circuitry requires that the Fluid Warmer is at operating temperature (41°C). Once this is established, press and hold the button. Then, release the button. The Over Temperature alarm continues to function. Clear the alarm mode by turning the device off, then back on. See Section 11, *Testing*, for instruction on performing an Over Temperature Test.

4 **Fluid Warmer Alarm Signal Test Button**
The Fluid Warmer Alarm Signal Test is used to confirm proper operation of the visual and audible alarm indicators. Press and hold this button to test circuitry. Then, release the button. The Over Temperature alarm continues to function. Clear the alarm mode by turning the device off, then back on.

5 **Reservoir Capacity**
Capacity for recirculating solution reservoir is 1.4 liters. Use recirculating solution. Do not exceed maximum capacity.

Fluid Warmer Display Panel

The Fluid Warmer Display Panel provides continuous information about the operation of the Fluid Warmer. A liquid crystal display (LCD) indicates recirculating solution temperature. Just below the LCD, four light-emitting diodes (LEDs) indicate operation modes for the device. For identification purposes, the diodes are shown illuminated.



1 **Recirculating Solution Temperature**
The temperature of the recirculating solution is displayed in the LCD panel. The temperature is displayed in degrees Celsius.

Note: *This is NOT the temperature of fluid delivered to the patient—the display reflects the temperature of the recirculating solution.*

2 **Automatic Operation LED**
The green LED indicator illuminates when the power is ON and the Disposable Set has been properly installed. When lit, this indicates the Fluid Warmer is operating.

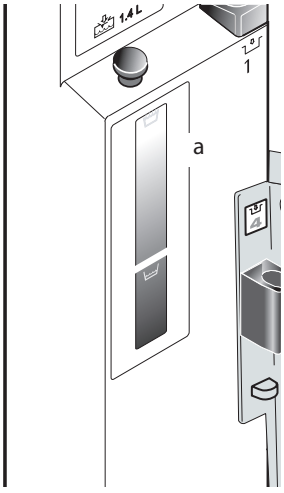
3 **Check Disposables LE**D
The yellow LED indicator illuminates and an audible attention signal beeps when the Disposable Set is not properly installed. See the Interlocks description in this section for directions on clearing the Check Disposables alarm.

4 **Add Recirculating Solution LED**
The yellow LED indicator illuminates and an audible attention signal beeps when reservoir is low. Additional recirculating solution must be added to the reservoir. Maximum capacity for the reservoir is 1.4 liters of recirculating solution.

5 **Over Temperature LED**
The red LED indicator illuminates and an audible warning signal beeps when the recirculating solution is over the acceptable temperature for safe use.

Reservoir Level Display

The Reservoir Level Display has a clear window for viewing the amount of recirculating solution present in the reservoir. Check the reservoir to ensure the solution level is near the maximum level indicator (a). If the recirculating solution level is too low, the Add Recirculating Solution LED on the Display Panel illuminates and an audible attention signal beeps.

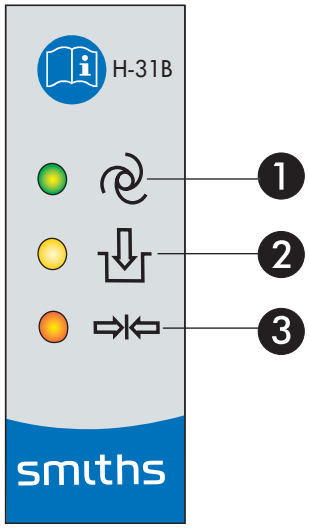


Air Detector/Clamp Control Panel and Alarms

H-1200

WARNING

Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the patient line to be delivered to the patient resulting in serious injury or death.



The Air Detector/Clamp Control Panel has three LED indicators that display the operational state of the Air Detector/Clamp. Refer to the figure.

1 **Automatic Operation LED**
The green Automatic Operation LED illuminates when the following conditions are present: The Fluid Warmer power is ON, a Disposable Set is properly installed in the Fluid Warmer and primed, the patient line from the Gas Vent/Filter Assembly is correctly placed in the #3 Clamp Slot, and the Clamp Slot door is closed.

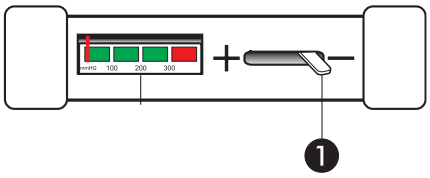
2 **Check Tubing LED**
The yellow Check Tubing LED illuminates and an audible attention signal beeps when the patient line tubing from the Gas Vent/Filter Assembly is not correctly placed in the #3 Clamp slot, and when the Clamp Slot door is not closed correctly.

3 **Clamped LED**
The red Clamped LED illuminates and an audible warning signal beeps when air is detected in the Gas Vent/Filter Assembly. The patient line is automatically clamped.

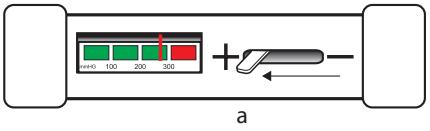
Pressure Chamber Control Panel

The Pressure Chamber Control Panel uses a control lever to switch from pressurized to unpressurized mode. A gauge displays pressure levels in the Pressure Chamber.

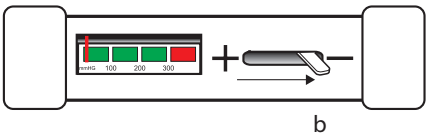
1 Pressurize / Unpressurize Lever
This lever is used to control the pressure mode in the Pressure Chamber.



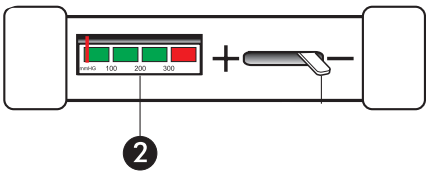
a To Pressurize the Pressure Chamber
With Pressure Chamber door closed and latched, slide lever to the left, all the way to the plus (+) pressurized position. This applies 300 mmHg pressure in the Pressure Chamber when the Fluid Warmer is turned ON.

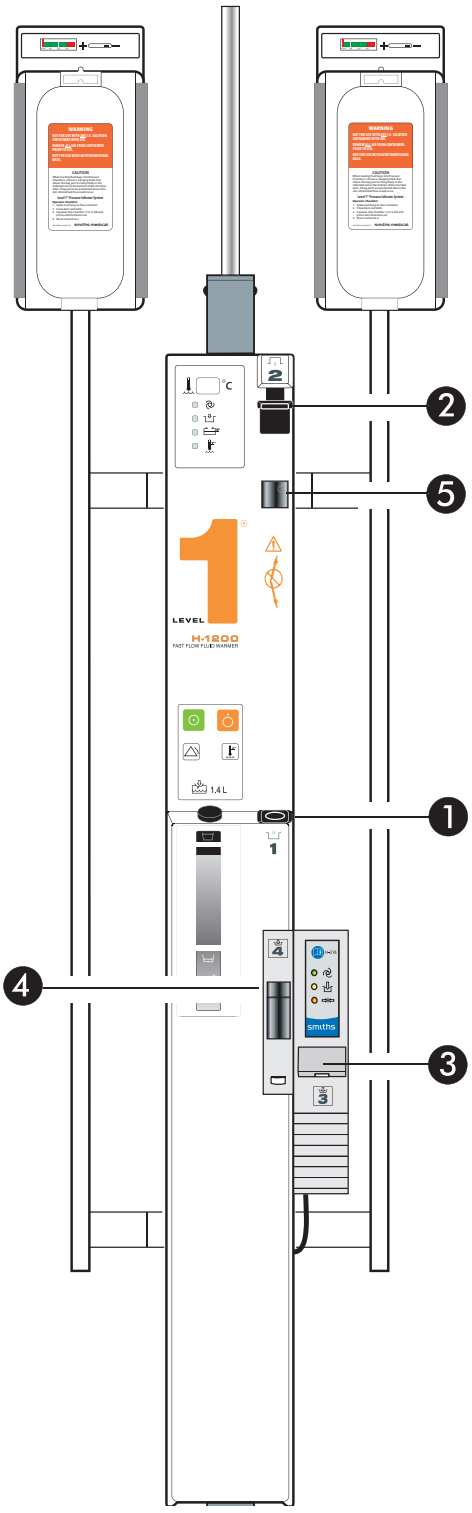


b To Unpressurize the Pressure Chamber
To remove pressure from the Pressure Chamber, slide the lever to the right, all the way over to the minus (–) unpressurized position. Pressure is released on the fluid bag in the Pressure Chamber.



2 Pressure Gauge
This gauge indicates the pressure present in the Pressure Chamber. When the Pressurize lever is in the plus (+) pressurized position and the Fluid Warmer is ON, this gauge displays the operating pressure in the Pressure Chamber. The operating pressure should be 300 mmHg.





Interlocks

The Fluid Warmer has five Interlocks that detect for proper installation of a Disposable Set's components. Refer to the figure to identify the positions of interlocks.

Note: *Block 1 is not an Interlock. It cannot detect if a Disposable Set is not correctly installed. It is identified here because it is an essential step for proper installation of the Disposable Set components.*

Three Interlocks are located on the Fluid Warmer and check for proper installation of:

- **2** Heat Exchanger, top end
- **4** Gas Vent/Filter Assembly
- **5** Heat Exchanger (guide)

H-1200

Two Interlocks are located in the Air Detector/Clamp 3 and check for the proper installation of:

Patient I.V. Line in the Clamp Slot
Door for the Clamp Slot

Interlocks **2**, **4**, and **5** prevent the Fluid Warmer's pump from circulating reservoir solution if the Disposable Set's Heat Exchanger and Gas Vent/Filter Assembly are not installed properly.

If Check Disposable Alarm is Activated on the Fluid Warmer

a Check Heat Exchanger for proper installation in Block 1, and Interlocks **2** and **5**.

b Press Heat Exchanger down firmly in Block 1 to secure in O-Ring.

c Press Interlock **2** tab down firmly to engage the Interlock switch.

d Press Heat Exchanger firmly into Interlock **5**.

e Check Gas Vent/Filter Assembly installation in Interlock **4**.

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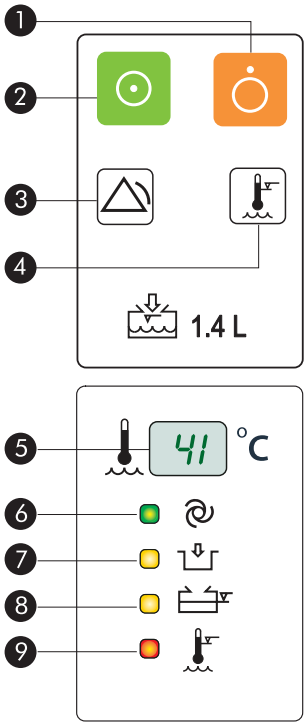
If Check Tubing Alarm is Activated on the Air Detector/Clamp

a Open the door and check the Patient Line for proper installation in the Clamp Slot at interlock **3**.

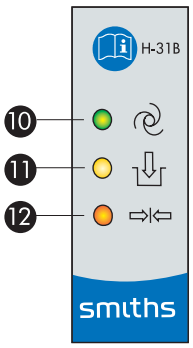
b Close the door and check that the tab on the top edge of the door is fully inserted into the Air Detector/Clamp at interlock **3** before pushing the door down to close it.

Operation Level 1® H-1200 Fast Flow Fluid Warmer

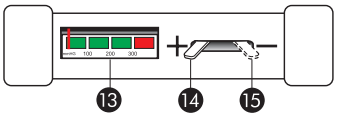


Function	Interface	#	Description	Indicator/Alarm Signal		
				Visible	Audible Beep	
Fluid Warming	Fluid Warmer Power and Alarm Test Panel	1	OFF	None	None	
		2	ON	LEDs display	None	
		3	Alarm Test	LEDs display	1/second	
		4	Over Temperature Alarm Test	LEDs display	1/second	
	Fluid Warmer Display Panel	5	Temperature Display	LCD Readout	None	
		6	Automatic Operation	Green LED	None	
		7	Check Disposables	Yellow LED: Medium Priority Alarm	1/5 seconds	62db
		8	Add Recirculating Solution	Yellow LED: Medium Priority Alarm	1/5 seconds	63db
		9	Over Temperature	Red LED: High Priority Alarm	1/second	65db

H-1200



Air Detection/ Clamping	Air Detection/ Clamp Alarm and Control Panel	10	Automatic Operation for Air Detection	Green LED	None	
		11	Check Tubing/ Patient Line	Yellow LED: Medium Priority Alarm	1/5 seconds	70db
		12	Air Detected/ Clamped	Red LED: High Priority Alarm	1/second	75db



Pressurized Fluid Delivery	Pressure Chamber Control Panel	13	Pressure Gauge	Numbered Dial	None	
		14	Pressurized	+ Symbol	None	
		15	Unpressurized	- Symbol	None	

SECTION 8

Operation

The Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) performs three primary functions; Fluid Warming, Air Detection/Clamping, and Pressurized Fluid Delivery. Functions are monitored and controlled by four interfaces/control panels located on the Fluid Warmer.
The four interfaces are:

- Fluid Warmer Power and Alarm Test Panel
- Fluid Warmer Display Panel
- Air Detector/Clamp Alarm and Control Panel H-1200
- Pressure Chamber Control Panel

In the table on the facing page, operation of the device is represented in terms of the four interfaces that control specific device functions. The numbers call-out individual Modes of Operation activated or indicated on the interface.

Functions

- Fluid Warming
- Air Detection/Clamping H-1200
- Pressurized Fluid Delivery

Operational modes

- OFF Mode
- ON/Automatic Operation for Fluid Warmer
- Alarm Test Mode
- Over Temperature Test Mode
- Check Disposables Mode
- Add Recirculating Solution Mode
- Over Temperature Alarm Mode
- Power ON Test for Air Detector/Clamp H-1200
- Automatic Operation Air Detector/Clamp H-1200
- Check Tubing Mode H-1200
- Air Detected/Clamped Mode H-1200
- Pressurized Mode
- Unpressurized Mode

The modes of operation are individually defined in the following section. This includes a description of each mode, activation and/or monitoring of the mode, mode characteristics, and clearing of the mode state.

Modes of Operation

WARNING

If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or user if this warning is not followed.

OFF Mode

Power is off only for a part of the equipment. The MAINS are still connected. Press the OFF button (**a**) on the Power and Control Panel to turn the device off.

a

ON/Automatic Operation Mode for Fluid Warmer

The Fluid Warmer enters Automatic Operating mode when a Disposable Set is properly installed and the device is turned ON. This is done by pressing the ON button (**b**).

b

Mode characteristics

- The green Automatic Operating LED on the Display Panel illuminates (**c**).
- Fluid warming begins.
- Pressure infusion is provided by activating the Pressure Chambers.
- Air Detector/Clamp enters the Power ON Test, then enters default Automatic Operation mode.

c

Alarm Test Mode

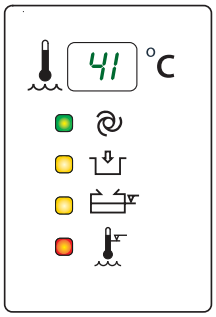
The Alarm Test mode is used to test the visual and audible indicators of the Level 1® H-1200 Fast Flow Fluid Warmer. This mode is entered by pressing and holding the Alarm Test button (**d**) on the Fluid Warmer's Control Panel.

d

Mode characteristics

- All visual indicators on the Fluid Warmer's Display Panel (**e**) illuminate.
- The Fluid Warmer's audible alarm beeps.
- When the Alarm Test button is released, the Over Temperature LED and an audible alarm remains active.
- To clear the Over Temperature alarm, turn the Fluid Warmer OFF and then back ON.

e



Over Temperature Test Mode


f

The Over Temperature Test mode is used to test the operation of the Fluid Warmer's Over Temperature Circuitry. This mode is entered by pressing and holding the Over Temperature Test button (**f**) on the Fluid Warmer Control Panel with the Fluid Warmer at operating temperature (41°C).


g

Mode characteristics

- The red Over Temperature LED (**g**) on the Display Panel illuminates.
- An audible warning signal beeps.

To Clear this mode

- Turn Fluid Warmer OFF.
- Turn Fluid Warmer back ON.

Temperature Display

The Temperature Display functions when the Fluid Warmer is powered ON. Temperature is displayed in degrees Celsius.

Check Disposables Mode

The Check Disposables mode of the Fluid Warmer indicates a missing or improperly installed Disposable Set.


a

Mode characteristics

- The Check Disposables yellow LED (**a**) on the Fluid Warmer's Display Panel is illuminated.
- An audible attention signal beeps.
- Reservoir solution circulation is stopped; fluid warming stops.
- Pressure Chambers continue to operate.

To Clear this mode

Install a disposable or check the disposable installation as follows:

- Check the position of the disposable in the #1 Block.
- Make sure the heat exchanger is seated in the heat exchanger guide.
- Press down firmly on the #2 Block.
- Check the position of the Gas Vent/Filter Assembly in the #4 Interlock.

Add Recirculating Solution Mode

The Add Recirculating Solution mode of the Fluid Warmer indicates that the solution level in the recirculating solution reservoir is below its minimum level.

Mode characteristics

- The yellow Add Recirculating Solution LED (**b**), on the Fluid Warmer's Display Panel, is illuminated
- An audible warning signal beeps.
- Solution circulation stops, fluid warming stops.
- Pressure Chambers continue to operate.
- Fluid flow to the patient continues.

b 

To Clear this mode

Add recirculating solution to the Fluid Warmer's reservoir.

Over Temperature Alarm Mode

The Over Temperature Alarm mode is entered when the temperature of the recirculating solution reservoir is at or above **43.9°C**

WARNING

Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in patient death or serious injury.

Mode characteristics

- The Over-Temperature LED warning light illuminates (**c**).
- An audible warning signal beeps.
- Solution circulation is stopped; fluid warming stops.
- Pressure Chambers continue to operate.
- Fluid flow to the patient continues.

c 

To Clear Over Temperature Alarm mode

Do the following:

- If connected to a patient, close all clamps.
- Turn OFF the Fluid Warmer to clear the alarm.
- Turn the power back ON.
- If the Fluid Warmer continues to alarm, remove from service. Contact Smiths Medical or your local Smiths Medical distributor.

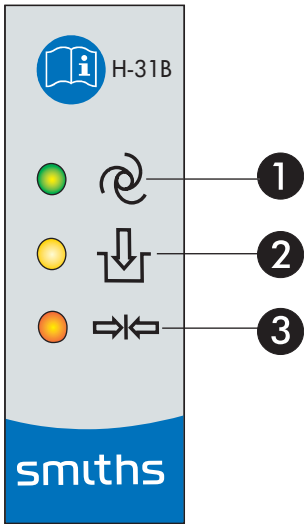
Power ON Test for Air Detector/Clamp

H-1200

The **Power ON Test** for the Air Detector/Clamp is activated when the Fluid Warmer is turned ON. This test activates the Air Detector/Clamp's visual and audible indicators.

Mode characteristics

- Audible alarm indicator beeps.
- All LED indicators on the Air Detector/ Clamp Control Panel illuminate:
  - **1** Automatic Operation LED indicator - Green
  - **2** Check Tubing LED indicator - Yellow
  - **3** Clamped LED indicator - Red



At the end of the Power ON Test the Air Detector/Clamp enters Automatic Operation mode. This is the default mode for the Air Detector/Clamp.

Automatic Operation Air Detector/Clamp

H-1200

In Automatic Operating mode, the Air Detector/Clamp monitors for the presence of air in the Disposable Set's Gas Vent/Filter Assembly. If air is detected the patient line is clamped off and an audible alarm beeps. The Air Detector/Clamp goes into Automatic Operation mode when the Fluid Warmer is turned ON and Disposable Set is properly installed and primed—no air is present in the Gas Vent/Filter Assembly.

Mode characteristics

- The green Automatic Operation LED (**1**) is illuminated.
- Monitoring for air in the Gas Vent/Filter Assembly is active.
- Fluid is ready to be delivered to the patient when in Automatic Operating mode.

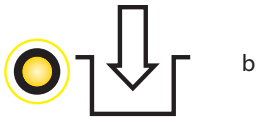
Check Tubing Mode

H-1200

The Air Detector/Clamp's Check Tubing mode is entered when the patient line from the Gas Vent/Filter Assembly is not properly installed in the Air Detector/Clamp Slot and when the Clamp Slot door is not closed correctly.

Mode characteristics

- The yellow Check Tubing LED (**b**) on the Air Detector/Clamp Control Panel is illuminated.
- An audible low-priority warning signal beeps.



To Clear this mode

- Place the patient line from the Gas Vent/Filter Assembly in the #3 Clamp Slot of the Air Detector/Clamp and close the Clamp Slot door.

H-1200

Air Detected/Clamped Mode

In this mode the Air Detector/Clamp is activated when the ultrasonic sensor detects the presence of air in the Gas Vent/Filter Assembly. Auditory and visual warnings are activated and the clamp is closed, preventing passage of fluid through the patient line.

Mode characteristics

- The patient line is clamped until alarm condition is removed.
- The red Clamped warning indicator LED (**c**) illuminates.
- The Air Detector/Clamp warning signal beeps.

c

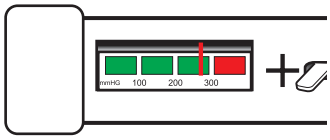
To Clear this mode

Perform the steps in Section 9, *Operating Instructions*, under the heading: Clear the "Air Detected" Alarm mode.

Pressure Display

The Pressure Display gauge (**a**) functions when the device is ON. The graduated indicator represents the level of pressure applied to the fluid bags. Pressure should be in the range of 280-300 mmHg pressure.

a

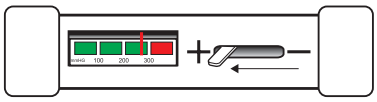


Pressurized Mode

The H-2 Pressure Chambers deliver fluids at an increased flow rate with the application of 300 mmHg pressure upon the fluid bags. Flow rate varies according to fluid type and viscosity, temperature, Disposable Set used, and the amount of clamping applied to the roller clamps.

Pressurized infusion is enabled when:

- A fluid bag is installed in the Pressure Chamber.
- The Fluid Warmer is turned ON.
- The Pressure Chamber switch is placed in the plus (**+**) pressurized position (**b**).



b

Mode characteristics

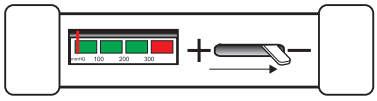
- The Fluid Warmer must be ON for the Pressure Chamber to work.
- Operating pressure should be between 280-300 mmHg.
- Pressure is not adjustable on the Pressure Chamber.
- Pressure is applied to the fluid bag in the Pressure Chamber.
- Pressure is indicated on the pressure gauge.

To Exit this mode

- Place the Pressure Chamber switch in the minus (**–**) unpressurized position (**c**).

Unpressurized Mode

Disable pressurization by moving the switch on the Pressure Chamber to the minus (–) unpressurized position (c).



c

Mode characteristics

- Pressure is released from the Pressure Chamber.
- A fluid bag can be removed or loaded into the Pressure Chamber.

SECTION 9

Operating Instructions

The Operating Instructions are grouped into five segments. Read through each section BEFORE performing a procedure.

WARNINGS

- **The Fluid Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and D or DI series Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets resulting in death or serious injury to the patient or user.**
- **When injecting medications into the fluid path, do not inject through the triple-lumen tubing of the Level 1® D/DI-60HL Disposable Set. This may allow communication between the recirculating solution path and I.V. fluid path, which could result in death or serious injury to the patient.**
- **Replace Gas Vent/Filter Assembly every three hours, or when the filter becomes clogged, or when air is slowly vented. Failure to do so will result in a reduction of flow rate. This may result in inadequate patient treatment resulting in death or serious injury to the patient.**
- **The replacement Gas Vent/Filter Assembly must be fully primed before continuing infusion. Failure to do so may allow air to be infused into the patient resulting in death or serious injury to the patient.**
- **Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle resulting in death or serious injury to the patient or user.**
- **Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution path and I.V. fluid path, resulting in the I.V. delivery of inappropriate fluids which could result in death or serious injury to the patient.**
- **The tubing must be properly placed in the Clamp Slot of the Air Detector/Clamp. Failure to ensure that the tubing is correctly positioned in the Clamp Slot may result in failure to stop air infusion which may result in patient death or serious injury.**

9.1 Set Up for Use

WARNINGS

- **Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions, could result in death or serious injury to the patient or user.**
- **Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Set if Luer and spike caps are not securely in place, or if Luer connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.**
- **Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets, which could result in death or serious injury to the patient.**

A – Install the Disposable Administration Set

The installation sequence for the Disposable Administration Set corresponds to the numbered Blocks marked 1-2-3-4 on the H-1200 Fast Flow Fluid Warmer Fluid Warmer) and 1-2-3 on the H-1000 Fluid Warmer.

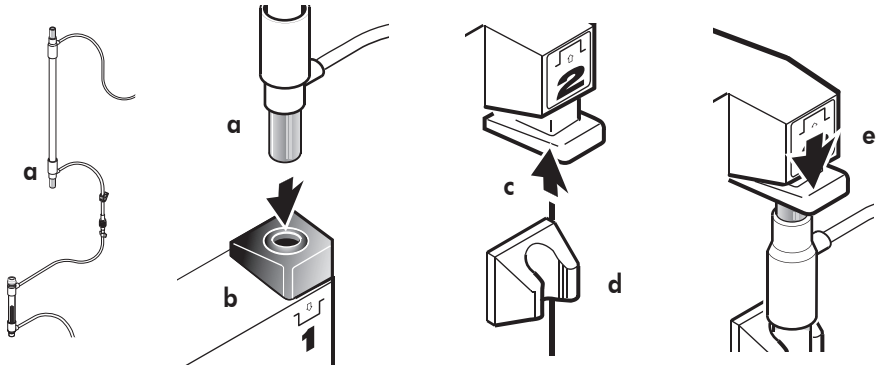
Remove the Disposable Set from its packaging and review the Instructions for Use provided. Do not remove spike caps or Luer caps at this time.

Note: *Inspect the Disposable Set prior to use and confirm Luer connections are secure.*

1. Push the bottom end of the Heat Exchanger (**a**) [the end near the Gas Vent/Filter Assembly] into #1 Block (**b**). Press the Heat Exchanger down firmly to properly seat in the block.

   Note: *D/DI-60HL Disposable Sets require the Heat Exchanger to be placed with the Patient Line extending to the left.*

2. Slide #2 Block up (**c**). Snap Heat Exchanger into guide (**d**). Press firmly into place to ensure it is properly seated. Slide #2 Block down (**e**), push down firmly to secure.

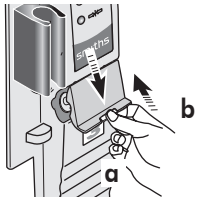


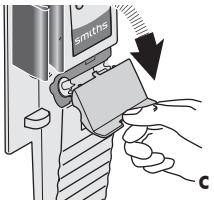
3 Move the pinch clamp on the Patient Line of the Gas Vent/Filter Assembly next to the Luer connector. Close the pinch clamp.

4 Install the Gas Vent/Filter Assembly. H-1000

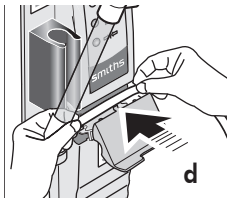
- **a** Align the Gas Vent/Filter Assembly to the #3 Block, and press it into place.
- **b** Press the green Power ON button, located on the Power and Alarm Test Panel, to turn ON the Fluid Warmer.

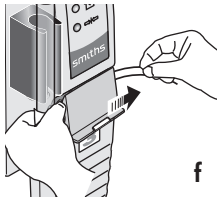
5 Install the Gas Vent/Filter Assembly. Refer to the series of figures. H-1200

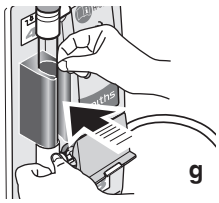




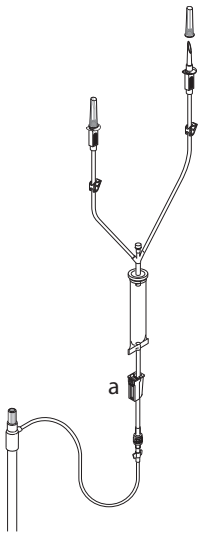
- **a** Open the #3 Clamp Slot door by pushing down on tab, (**a**) and lifting up the front of the door (**b**).
- **b** Pull the door down (**c**) and away from the Clamp Slot.
- **c** Insert the Patient Line in the Clamp Slot (**d**) and push it back into the slot.
- **d** Hold the Patient Line in the Clamp Slot and push the door up (**e**) to engage the top hinge. Then push the front of the door down to close it.
- **e** Pull the Patient Line to the right (**f**) to align it in the Clamp Slot without kinking.
- **f** Align the Gas Vent/Filter Assembly to the #4 Block, (**g**) and press it into place.







B – Prime the Disposable Administration Set

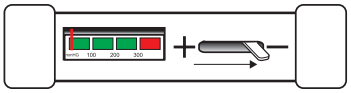


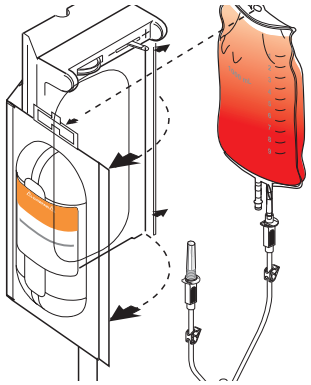
1 Close the Disposable Set clamps above the Heat Exchanger.

- For DI-50, D/DI-60HL, D/DI-70 Disposable Sets,
  – close pinch clamps below the bag spikes, and
  – close roller clamp below the drip chamber (**a**).
- For D/DI-100, D/DI-300 Disposable Sets
  – close pinch clamps below the drip chambers.

2 Remove all air from the fluid bag:

- **a** Invert solution bag.
- **b** Use aseptic technique. Pierce membrane of bag port with spike of Disposable Set. Then withdraw spike.
- **c** Squeeze bag to exhaust ALL air.
- **d** Place spike in bag port. Do not allow air to re-enter bag.
- **e** Repeat this step for each fluid line to be used.





3 Slide lever on H-2 Pressure Chamber to the minus (–) unpressurized position.

4 Hang spiked fluid bag/s in Pressure Chamber:

- **a** Release hinged latch, open door and hang fluid bag inside on tab appropriate for bag size.
- **b** Close the door and secure latch.
- **c** Injection and Spike ports on the fluid bag should extend from opening at the bottom of the Pressure Chambers without being obstructed.

Note: *When installing Level 1® D/DI-300 series Disposable Sets, hang the third fluid bag from the I.V. pole.*

CAUTION

When loading fluid bags into H-2 Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur resulting in physical injury to the patient, user, and/or an adverse effect on the device or its performance.

5 Open clamp above Drip Chamber on Level 1® DI-50, D/DI-60HL, and D/DI-70 Disposable Administration Sets for each I.V. fluid bag being used to prime the drip chamber.

6 Prime Drip Chamber by squeezing drip chamber until one-half to three-quarters full of fluid.

Note:
- *DI-50, D/DI-60HL, D/DI-70 series use a single drip chamber.*
- *DIDI-100 and D/DI-300 series use a separate drip chamber for each spiked bag. The clamp is below the drip chamber.*

7 Open remaining clamps above the Heat Exchanger. Fluid flows into the Gas Vent/Filter Assembly.

8 Vigorously tap the Gas Vent/Filter Assembly to dislodge air bubbles from filter screen.

H-1200

9 Press the green Power ON button, located on the Power and Alarm Test Panel, to turn ON the Fluid Warmer.

- The Air Detector/Clamp runs a Power ON Test.
- All Air Detector/Clamp indicator LEDs illuminate.
- The audible warning beeps.
  – If the above does not occur, remove the device from service.
- Upon completion of the Power On Test the Air Detector/Clamp enters Operation mode with the Automatic Operation LED illuminated.

- If the Disposable Set is incorrectly installed, the Fluid Warmer's Check Disposables attention indicator illuminates and the audible attention signal beeps. Check the installation of the Disposable Set following the directions provided in Section 6, *Controls and Displays*, on Interlocks.

C – Prime the Patient Line

1 Remove the male Luer cap from the distal end of the Patient Line.

Note*: On Level 1® D/DI-60HL Disposable Administration Sets (D/DI-60 HL Disposable Sets), verify that no recirculating solution comes out of the distal end of the Patient Line.*

WARNING

If fluid exits the Patient Line of the D/DI-60HL Disposable Set, replace the Disposable Set.

2 Open the pinch clamp below the Gas Vent/Filter Assembly.

3 Allow fluid to flow until no air is observed in the Patient Line and the line is primed with fluid. Then, close the roller clamp on the Patient Line.

Note: *On D/DI-60HL Disposable Sets close roller clamp below Drip Chamber.*

D – Test the Audible and Visual Alarms

Test the visual and audible alarm signals by performing the following steps.

1 Press and hold the Alarm Test button on the Fluid Warmer's Power and Alarm Test Panel.

- All Fluid Warmer visual alarm LEDs illuminate and the audible alarm signal beeps.

2 Release the Alarm Test button; the Over Temperature alarm continues.

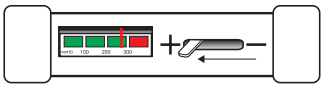
3 Clear the Over Temperature alarm condition.

- Turn the Fluid Warmer OFF, then ON.
- The Air Detector/Clamp runs a Power On Test.
- The Air Detector/Clamp goes into Automatic operation.

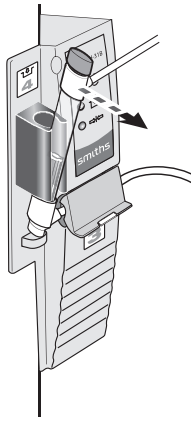
H-1200 E – Test the Air Detector/Clamp

WARNING

The functional test for the Air Detector/Clamp accessory must be performed before each use. If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Fully functional visual and audible alarm systems are essential for the safe use of the Air Detector/Clamp.



1 Slide the lever on the Pressure Chambers to the plus (+) pressurized position to pressurize fluid delivery.



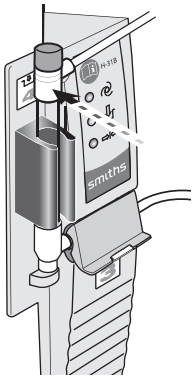
2 Move the top of the Gas Vent/Filter Assembly away from the Air Detector sensor as shown.

3 The following occurs:

- The Air Detector clamp closes.
- The red Clamped indicator LED illuminates.
- The audible warning signal beeps.
- Fluid Warmer disposable alarm activates.

If any of the above does not occur, remove the device from service.

4 Open the roller clamp on the Patient Line to verify that fluid does not flow. After verifying that no fluid is flowing, close the roller clamp completely. If fluid flow is observed, remove the device from service.



5 Return to normal operation by pressing the top of the Gas Vent/Filter Assembly back into the #4 Block.

6 The Air Detector/Clamp resumes Automatic Operation mode.

- The green Automatic Operation LED on the Air Detector/Clamp Control Panel illuminates.

7 The Fluid Warmer is now ready for patient connection. Unclamp Patient Line to begin infusion.

Note: *On D/DI-60HL Disposable Sets open roller clamp below drip chamber.*

Conclusion

This concludes Section 9.1, Set Up for Use. Operators can proceed to the next Section 9.2, *Use of the Fluid Warmer*.

WARNINGS

- **Remove all air from the fluid bags before spiking and the fluid lines before connecting to the patient. Failure to do so can result in infusion of air into the patient resulting in death or serious injury to the patient.**
- **Do not reuse partially full fluid bags. Fluid bags that have been partially drained, un-spiked, and then reinstalled may contain air, which if used can result in infusion of air into the patient resulting in death or serious injury to the patient. Use only new fluid bags from which the air has been removed.**
- **Replace Gas Vent/Filter Assembly every three hours, or when the filter becomes clogged, or when air is slowly vented. Failure to do so will result in a reduction of flow rate. This may result in inadequate patient treatment resulting in death or serious injury to the patient.**
- **The Replacement Gas Vent/Filter Assembly must be fully primed before continuing infusion. Failure to do so may allow air to be infused into the patient which could result in patient death or serious injury.**

CAUTION

When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur resulting in physical injury to the patient, user, and/or an adverse effect on the device or its performance.

9.2 Use of the Fluid Warmer

Use of the Fluid Warmer requires that the steps in Section 9.1, *Set Up for Use* have been completed.

Overview

Use of the Fluid Warmer involves the following steps:

1. Load the Pressure Chambers
2. Pressurize the Pressure Chambers
3. Make patient connection, begin infusion
4. Replace Gas Vent/Filter Assembly
5. Change fluid bag

Step 1—Load the Pressure Chambers

a Turn the hinged latch on the right side of the Pressure Chamber outward. Open the door.

b Hang a solution bag on the appropriate hanging hook inside the door. The Pressure Chamber can hold bags of varying sizes.

- On the inside of the Pressure Chamber door are hooks for bags smaller than 1000ml.
- On the top of the Pressure Chamber door are hooks appropriate for 1000ml bags.
- Bags from different fluid manufacturers vary somewhat in their dimensions.
- Choose a hanging hook that allows the bag drain port to hang freely in the indented slot at the bottom of the Pressure Chamber door.

c Close the door and secure side latch.

Step 2—Pressurize the Pressure Chambers

a Turn ON the Pressure Chamber by moving the lever located at the top of the Pressure Chambers over to the plus (+) pressurized position.

b Check gauge to ensure pressure of 280-300 mmHg is achieved.

- Pressure in the chambers is not adjustable.

Note: *Power must be ON for the Pressure Chambers to operate.*

WARNING

Blood and blood products could contain pathogenic organisms. Failure to follow Institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens which could result in user death or serious injury.

Step 3—Make Patient Connection

Make patient connection and begin infusion.

Step 4—Replace the Gas Vent/Filter Assembly

Replace the Gas Vent /Filter Assembly every 3 hours, when the filter becomes clogged, or if air is venting slowly. Refer to Section 9.3, *Replace the Gas Vent/Filter Assembly*.

Step 5—Change the Fluid Bag

a Move the lever on the Pressure Chamber over to the minus (–) unpressurized position. This will release the pressure in the Pressure Chamber and deflate the bladder.

Close ratchet clamp under empty bag.

b Open door and remove the fluid bag from the Pressure Chamber.

c Remove the spike from the used fluid bag.

d Remove any air from the new fluid bag and spike the fluid bag.

e Hang the new fluid bag in the Pressure Chamber. Close and latch the door.

f Move the lever on the Pressure Chamber over to the plus (+) pressurized position to pressurize the chamber.

g Open ratchet clamp.

9.3 Replace the Gas Vent/Filter Assembly

Use one of the following Gas Vent/Filter Assemblies:

- F-30 Gas Vent/Filter Assembly for D/DI-300 Disposable Sets
- F-10 Gas Vent/Filter Assembly for all other Fast Flow Disposable Sets

1 Close all clamps above and below the Gas Vent/Filter Assembly on D/DI-series Disposable Set and on new Gas Vent/Filter Assembly.

2 Turn the Fluid Warmer OFF.

3 Remove the **used** Gas Vent/Filter Assembly while still connected to the Disposable Set:

a Remove Gas Vent/Filter Assembly from the #3 Block. H-1000

b Remove Gas Vent/Filter Assembly from the #4 Block. H-1200

c Open the #3 Clamp Slot door and remove the Patient Line from the Clamp Slot. H-1200

4 Install the **new** Gas Vent/Filter Assembly:

a Press the Gas Vent/Filter Assembly into the #3 Block. H-1000

b Insert the patient line in the Clamp Slot. H-1200

c Close the Clamp Slot door. H-1200

d Align the patient line in the Clamp Slot without kinking. H-1200

e Press the Gas Vent/Filter Assembly into the #4 Block. H-1200

5 Using aseptic technique:

   a Disconnect the upper Luer fitting on the **used** Gas Vent/Filter Assembly.

   b Remove the upper Luer end cap on the **new** Gas Vent/Filter Assembly.

   c Connect the Disposable Set to the **new** Gas Vent/Filter Assembly inlet.

6 With the lower clamp on the **new** Gas Vent/Filter Assembly closed, open all clamps above Gas Vent/Filter Assembly. The Gas Vent/Filter Assembly will self prime.

7 Turn power ON.

8 Remove the end cap on the lower patient line of the **new** Gas Vent/Filter Assembly. Slowly release the lower clamp and allow the lower patient line to fill completely.

9 Close the clamp after the line is full.

10 Holding the **used** Gas Vent/Filter Assembly horizontally, disconnect the Luer lock on the lower patient line. Connect the Luer lock fittings on the **used** Gas Vent/Filter Assembly together and discard.

11 Connect the Luer Lock on the lower patient line of the Gas Vent/Filter Assembly to the patient line.

12 Open clamps below the Gas Vent/Filter Assembly and resume infusion.

9.4 Activated Alarms

Refer to Section 8, *Operation* for information on identifying Alarm states, conditions that activate them, and methods for clearing Alarm states.

H-1200

A. "Air Detected" Alarm mode

Detection of air in the Gas Vent/Filter Assembly results in the following:

- The patient line is clamped off
- The red Clamped LED warning signal illuminates
- The audible warning signal beeps

WARNING

- **Activation of the Air Detector/Clamp Alarm during infusion indicates that fluid flow has stopped and that immediate operator intervention is required to restore fluid flow. Failure to reinstate flow (after purging any air or foam) may result in patient death or serious injury.**

- **Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the patient line to be delivered to the patient resulting in serious injury or death.**

B. Clear the "Air Detected" Alarm mode: H-1200

1. Immediately close all clamps on the Disposable Set.
2. Remove pressure from the Pressure Chambers by moving the lever to the minus (–) unpressurized position.
3. Inspect the entire Disposable Set for the presence of air, locate the source of the air, and remove it.

   Note: *Air or foam may have been vented through the Gas Vent/Filter Assembly.*
4. Remove any remaining air from the Disposable Set:
   - **a** Insert spike into an air-free bag/s of I.V. solution.
   - **b** Place the I.V. bags in the Pressure Chamber/s; close and secure the door.
   - **c** Move the lever to the plus (+) pressurized position to pressurize the Chamber/s.
   - **d** Prime the drip chamber/s and open the Disposable Set clamps above the Gas Vent/Filter Assembly.
   - **e** Fluid flows freely through the tubing. Air in the I.V. line is vented out through the Gas Vent/Filter Assembly. When air is no longer present in the Gas Vent/Filter Assembly, the Clamp opens and resumes automatic operation mode.

   Note: *If air is not freely vented, replace the Gas Vent/Filter Assembly.*

Refer to Section 9.3, *Replace the Gas Vent/Filter Assembly.*

5. If no warning signals are active, the Fluid Warmer with Air Detection and Pressure Chambers is ready for use.
6. Open the remaining Disposable Set clamps, slowly open the roller clamp, and reestablish fluid flow to the patient.

For more information on the following alarm conditions, refer to Section 8, *Operation*:

- Over Temperature Alarm
- Check Disposables Alarm
- Check Tubing Alarm
- Add Recirculating Solution Alarm

9.5 After Use

1. Discontinue infusion.
2. Turn the Fluid Warmer OFF.
3. Release chamber pressure before opening the Pressure Chamber door:
   a. Move the lever to the minus (–) unpressurized position. This will release the pressure in the chamber and deflate the bladder.
   b. Open door and remove the fluid bag.
4. Remove the Disposable Set from the Fluid Warmer.
5. Dispose of the Disposable Set in a safe manner according to local guidelines for disposal of contaminated medical waste.
6. Visually check the condition of the device. Remove from service any unit that shows physical damage.
7. Clean the device with warm soapy water.

SECTION 10

Troubleshooting

Only competent personnel should perform any routine maintenance and repairs to the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer).

The following two tables feature general troubleshooting information along with slow flow rate troubleshooting.

General Troubleshooting Guide

Problem	Check the following:
No Power	Check to see if unit is plugged in and power is turned ON. Be sure the unit is plugged into a working MAINS receptacle.
Disposables Alarm beeps	Check to see that the Heat Exchanger and Gas Vent/Filter Assembly are properly installed.
Add Recirculating Solution Alarm	Fill reservoir to the maximum reservoir level with recirculating solution.
Over -Temperature Alarm beeps	If connected to a patient, close all clamps. Press OFF button to clear alarm. Then, press ON button to power on. If the Fluid Warmer continues to alarm, remove from service. Contact Smiths Medical or your local Smiths Medical distributor.
Hot Cabinet	Check the air inlet on the bottom of the unit. Remove any blockage or dust to insure adequate air flow.
Heat Exchanger hard to install	Lubricate O-Rings in #1 and #2 block heat exchanger sockets with silicone lubricant. Silicone lubricant part # 80-04-002.
Loud Compressor	Verify pneumatic tubing is fully seated into fittings.
LED doesn't light up during set up (on Fluid Warmer or Air Detector/Clamp)	1. Verify unit is plugged into MAINS. 2. If still no LED illumination, discontinue use of the medical device and remove from service.
Tubing doesn't fit in Air Detector/Clamp	Verify Tubing is Level 1® D/DI Series tubing.

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Slow Flow Rate Troubleshooting

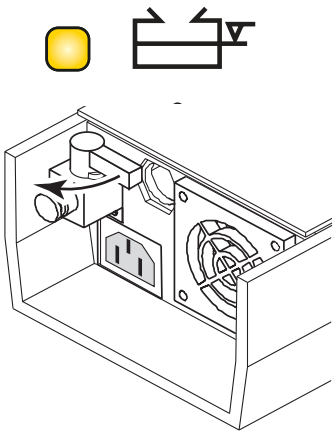
Problem	Check the following:
Pressure Chambers not activated	Verify the Fluid Warmer is ON. Verify the Pressure Chamber levers are fully in the plus (+), pressurized position. Verify pneumatic tubing is fully seated into fittings on the Pressure Chambers and Fluid Warmer.
Blood develops particulate	Stored blood develops particulate. If blood is older than 5-7 days, consider using Level 1® PF-1 pre-filters.
Clogged filter	Change Gas Vent/Filter Assembly if filter becomes clogged.
Fluid bag not fully spiked or bag port twisted	Make sure the membrane of the fluid bag port is fully pierced by the bag spike and that the neck of the bag port is not twisted.
Non-Level 1® bag port filters	40 to 80 micron filters used between the bag port and the spikes of the Disposable Set may restrict flow. Consider using Level 1® PF-1 pre-filters (340 micron).
Clamps partly engaged	Verify all clamps are fully open.
Clamps left in the clamped position for long periods	Leaving clamps fully clamped for long periods will cause the tubing to become deformed. Do not leave clamps closed for extended periods of time.
Kinked tubing	Verify that no tubing kinks are present.
Air trapped on filter screen of Gas Vent/ Filter Assembly	Remove Gas Vent/Filter Assembly and tap against the cabinet of the Fluid Warmer to dislodge air bubbles, allowing them to vent. If this fails to correct problem, replace with new Gas Vent/ Filter Assembly.
Non-high flow extension lines	Use only extension lines with an inner diameter of 0.13" (3.3 mm) or larger, such as Level 1® X-36 or Y-30 extension sets.
Stopcock	Use only Level 1® SC-3 (9 french inner diameter).
Small gauge needle or catheter	Use large bore needles or catheters to maximize flow rates.

H-1200

SECTION 11

Testing

This unit should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by competent personnel. If competent personnel are not available, contact Smiths Medical. If the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) and installed accessories do not pass the tests, discontinue use of the medical device and remove from service. Contact Smiths Medical or your local Smiths Medical distributor. Testing requires a Level 1® Disposable Administration Set (Disposable Set) to be installed in the Fluid Warmer.



Add Recirculating Solution Alarm

The Fluid Warmer is equipped with a float switch that senses the level of the recirculating solution in the reservoir. When the solution level is too low, an LED on the Display Panel illuminates and an audible alarm beeps. In the Add Recirculating Solution Alarm mode, the circulating pump is not running. With a Disposable Set in place and the unit turned on, test the Add Recirculating Solution Alarm by draining the solution until the level has dropped below the minimum reservoir level. The Add Recirculating Solution Alarm should activate. To drain recirculating solution from the Fluid Warmer, turn the drain valve, on the bottom of the unit 90 degrees clockwise and allow some of the recirculating solution to drain into a container.

Check Disposables Alarm

Five Interlocks detect the proper installation of an Disposable Set in the Fluid Warmer. If a Disposable Set is not properly installed and the power is ON, an indicator will illuminate and an audible alarm beeps. With the Fluid Warmer ON, the Interlocks should be tested one at a time by performing the following steps.

1. Top Heat Exchanger Socket – Slide the #2 Block up slowly. The Check Disposables indicator will illuminate and the audible alarm beeps.
2. Heat Exchanger Interlock – Gently pull on the middle of the heat exchanger. The Check Disposables indicator will illuminate and the audible alarm beeps.
3. Gas Vent/Filter Assembly Interlock – Pull the top of the Gas Vent/Filter Assembly from the Block. The Check Disposables indicator will illuminate and the audible alarm beeps.

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4 #3 Check Tubing Interlock on the Air Detector/Clamp – Remove the tubing from the Clamp Slot and close the door. The Check Tubing alarm signal on the Air Detector/Clamp is activated and the audible alarm beeps.

H-1200

5 #3 Check Door Closed Interlock on the Air Detector/Clamp – With tubing installed in the Clamp Slot, open the door. The Check Tubing alarm signal on the Air Detector/Clamp is activated and the audible alarm beeps.

Over Temperature Test

Do the following

1 Insure that the Fluid Warmer is at operating temperature (41°C).
2 Press and hold the Over Temperature Test button (**a**).
3 The Over Temperature LEDs illuminate, and an audible alarm beeps.
4 Release the Over Temperature Test button.
5 Over Temperature LED and audible alarm signal remains active.

a

Clear the Alarm mode

1 Turn the Fluid Warmer OFF.
2 Turn the Fluid Warmer back ON.

Fluid Warmer Alarm Signal Test

The Alarm Test button is used to confirm proper operation of the visual and audible alarm indicators.

Do the following

1 Press and hold the Alarm Test button (**b**).
2 The LED illuminates, and an audible alarm beeps.
3 Release the Alarm Test button.
4 Over Temperature LED remains lit, and the audible alarm continues to beep.

b

Clear the Alarm mode

1 Turn the Fluid Warmer OFF.
2 Turn the Fluid Warmer back ON.

Performance Testing

Cold Start Test

Store the Fluid Warmer unit in a room where the room temperature is approximately 21°C (70°F).

1 Put a Disposable Set in place.
2 Record the start time.
3 Turn the Power button ON.

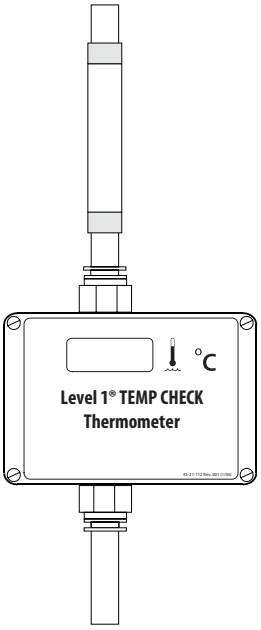
- The green system operational indicator illuminates.
- The Air Detector/Clamp goes through the Power ON Test.
- Rapidly rising numbers will appear on the recirculating solution temperature display.
- Within 60 seconds (±) the display should read at least 30°C.
- In 3 to 10 minutes the display should read 41°C.

The Temperature Set Point is 41.7°C (+/– 0.3°C).

Note: *If the Fluid Warmer does not pass the Cold Start Test, it should be removed from use and returned to Smiths Medical or your local Smiths Medical distributor.*

Calibration Test

The approved way to confirm proper calibration of the recirculating solution temperature is to use the Level 1® DSTA-40 TEMPCHECK (Part Number 80-01-040).



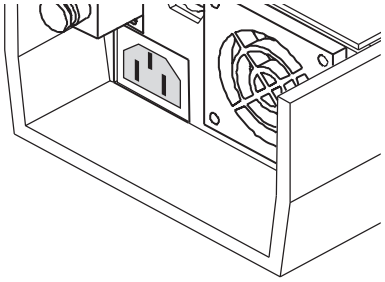
Calibration Test with DSTA-40

The DSTA-40 TEMPCHECK (DSTA-40) is an electronic thermometer used to verify the recirculating solution operating temperature of the Fluid Warmer. The DSTA-40 uses thermistor technology to sense the temperature of the recirculating solution temperature for the Fluid Warmer. The recirculating solution temperature is displayed by a liquid crystal display (LCD). The DSTA-40 is powered from the auxiliary outlet of the Fluid Warmer. No batteries are required.

Note: *The Level 1® DSTA-40 TEMPCHECK is available for purchase from Smiths Medical.*

Proper Calibration of Recirculating Solution Temperature

Confirm proper calibration of recirculating solution temperature by performing the following steps:



1. Plug the DSTA-40 into the auxiliary outlet located on the bottom of the Fluid Warmer.
2. Install the DSTA-40 in the heat exchanger position (#1 Block and #2 Block).
3. Install a test filter in the #4 Block.
4. Turn the Fluid Warmer ON. Allow to warm up until the DSTA-40 temperature display stabilizes.
5. Compare the DSTA-40 temperature display with the temperature display on the Fluid Warmer's Display Panel.

   Note: *The Fluid Warmer's temperature display must read within 0.3°C of the Level 1® DSTA-40 TEMPCHECK display on a properly calibrated unit.*

   If the DSTA-40 reads 41.7°C and the Fluid Warmer's temperature display is within the range of 41.4°C-42.0°C, the calibration is OK.

Periodic Electrical Testing

Earth Leakage

The Fluid Warmer must be tested in accordance with IEC 60601-1:2005. The earth leakage current test should be performed with the immersion heater circuit in the full ON condition; for this reason the leakage current test should be performed on units which have room temperature recirculating solution in the reservoir. Units not meeting this standard should be returned to Smiths Medical or your local Smiths Medical distributor.

Ground Continuity

The Fluid Warmer must be tested in accordance with IEC 60601-1:2005.

WARNING

Grounding reliability can be achieved only when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle resulting in death or serious injury to the patient or user.

SECTION 12

Maintenance

Only competent personnel should perform any routine maintenance and repairs to the Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer). Maintenance is scheduled prior to each use, every 30 days, and annually. The tasks are detailed below.

Note: I*f distilled water is used as the recirculating solution, change the solution every 30 days. If a 0.3% hydrogen peroxide/distilled water solution is used as the recirculating solution, change the solution every 12 months, and during the 12 month period, always refill the reservoir with a 0.3% hydrogen peroxide/distilled water solution*.

Maintenance Performed Prior to Every Use

Clean and inspect the Fluid Warmer with Air Detector/Clamp and Pressure Chambers after each use.

Clean the Exterior

Clean the entire Fluid Warmer after every use.

CAUTIONS

- **Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the Fluid Warmer.**
- **Do not place the Fluid Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the Fluid Warmer or into the external connectors.**

1. Unplug the Fluid Warmer before servicing.
2. Visually inspect the Fluid Warmer to ensure there is no visible damage or deterioration of the enclosure such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect. Contact Smiths Medical or your local Smiths Medical distributor.
3. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out excess solution so that the applicator is not dripping. Wipe or scrub the entire surface of the enclosure and control panels. Use a soft brush to clean the power cord if necessary.
4. Rinse a separate soft cloth or sponge in room temperature running potable water. Squeeze out excess water so that the

applicator is not dripping. Wipe all of the aforementioned surfaces. Repeat rinsing the cloth or sponge several times with fresh running water during this process to insure all visible residue is removed.

5 Dry the item with a hand towel or soft cloth.

6 Visually inspect the Fluid Warmer and its components to insure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary.

7 After thoroughly cleaning the Fluid Warmer, perform disinfection if required.

8 If it is hospital policy to perform disinfection as part of reprocessing, then follow your institution's guidelines for disinfecting of the surfaces of non-critical medical devices. The list below includes low-level disinfectants that are commonly used in the medical community and high-level disinfectants that are claimed by the manufacturer. The effectiveness of these listed disinfectants should be validated using the hospital procedures.

The following disinfectant agents can be used without causing damage to the enclosure:

Low Level Disinfectants:

- fantastik® All Purpose Cleaner

High Level Disinfectants:

- 1.59% Phenol (e.g., Sporicidin®)
- 3.4% Glutaraldehyde (e.g., CIDEX® Plus)
- 10% Bleach solution
- 1% Ammonia solution
- Surface disinfectants compatible with plastic or metal materials

9 Rinsing of the disinfectant residue should be done using a soft cloth or sponge as the applicator.

General Inspection

- Check the condition of the Fluid Warmer with a visual inspection. Remove from service any unit that shows physical damage.
- If the Disposable Set does not install easily, lubricate the O-Rings as directed in the following section.

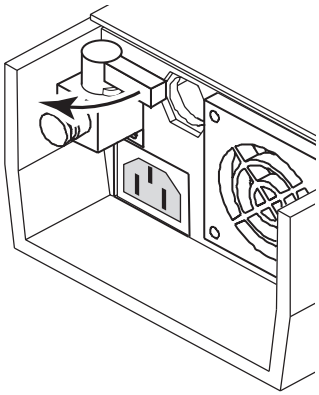
Maintenance Performed Every 30 Days

Lubricate O-Ring Seals

It is not necessary to disassemble the blocks to lubricate the O-Rings.

1 Place a small amount of silicone grease on a cotton swab.

2 Apply the silicone grease along the O-Rings in the bottom #1 Block, and top #2 Block Heat Exchanger sockets.



Change Recirculating Solution with Distilled Water

1 Place a container under the drain valve of the Fluid Warmer.

2 Drain the recirculating solution by turning the drain valve clockwise 90 degrees.

3 When all solution has drained from the reservoir, close the drain valve.

4 Refill the reservoir with distilled water. The reservoir holds 1.4 liters.

Maintenance Performed Every 12 Months

Disinfect the Recirculating Solution Reservoir

1 Place a container under the drain valve of the Fluid Warmer.

2 Drain the recirculating solution by turning the drain valve clockwise 90 degrees.

3 When all solution has drained from the reservoir, close the drain valve.

4 Remove the fill-port plug on the reservoir.

5 Prepare a 0.3% hydrogen peroxide/distilled water solution. Mix 140 ml of 3% hydrogen peroxide solution and 1,260 ml of distilled water.

6 Fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide/ distilled water solution.

7 Replace the fill-port plug.

8 Insert a Disposable Set into the Fluid Warmer.

9 Turn the Fluid Warmer ON. Let the solution circulate for a 30-minute disinfection period.

10 Turn the Fluid Warmer OFF.

11 Empty the reservoir.

12 Remove the Disposable Set and discard according to established hospital procedures

Change Recirculating Solution with a 0.3% Hydrogen Peroxide/Distilled Water Solution

1 Place a container under the drain valve of the Fluid Warmer.

2 Drain the recirculating solution by turning the drain valve clockwise 90 degrees.

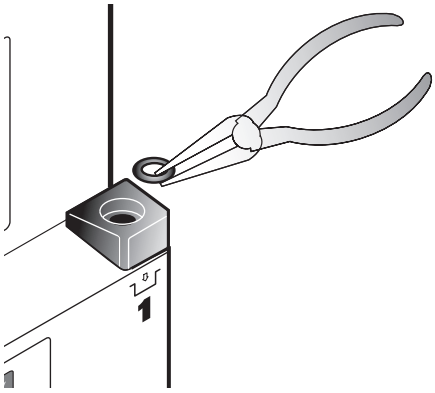
3 When all the solution has drained from the reservoir, close the drain valve.

4 Prepare a 0.3% hydrogen peroxide/distilled water solution. Mix 140 ml of 3% hydrogen peroxide solution and 1,260 ml of distilled water.

5 Fill the reservoir with 0.3% hydrogen peroxide/distilled water solution. The reservoir holds 1.4 liters.

Change O-Rings

Change the O-Rings in the #1 Block and #2 Block.



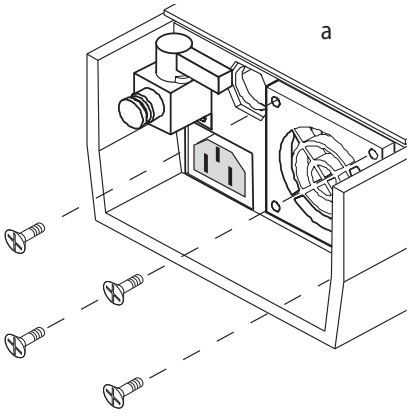
1 Remove each O-Ring from its socket by pulling it out with a pair of needle-nose pliers or by prying it out with a small screwdriver.

2 Lubricate the new O-Rings from the O-Ring Kit.

3 Press each O-Ring into its socket.

Clean Fan Filter

The Fan Filter (**a**) is located on the bottom of the Fluid Warmer. The fan guard snaps in place.



1 Remove four screws and unsnap the fan guard from the bottom of the unit.

2 Clean the filter with warm soapy water.

3 Replace the fan guard and filter.

Inspect Air Detector/Clamp

1 Check Clamp Cover Door for proper closure.

2 Check the Clamp Cover Door, Clamp Slot and Detector Head for structural integrity.

Inspect the Reservoir and Float Switch Assembly

Visually inspect the reservoir and float switch assembly for any signs of cracks or leaks.

Testing Fluid Warmer Operation

Perform all the tests described in the testing section of this manual. See Section 11, *Testing*.

- Add Recirculating Solution Alarm
- Check Disposables Alarm
- Over Temperature Alarm
- Performance Testing

Maintenance and Calibration Log

All maintenance and testing should be done by competent personnel. Regularly scheduled maintenance ensures proper functioning of the equipment. Refer to the table below for required tasks and frequency of routine maintenance.

Scheduled Maintenance and Calibration Checklist

Task	Every Use	Every 30 Days	Every 12 Months
Clean Exterior	☐		
General Inspection	☐		
Change Distilled Water		☐	
Lubricate O-Rings		☐	
Disinfect Recirculating Solution Reservoir			☐
Change 0.3% Hydrogen Peroxide Solution			☐
Replace O-Rings			☐
Clean Fan Filter			☐
Test Over Temperature Alarm			☐
Test Add Recirculating Solution Alarm			☐
Test Disposable Alarm			☐
Test Fluid Warmer Alarm Signal			☐
Verify Temperature Calibration			☐
Electrical Safety Tests			☐
Inspect the Reservoir and Float Switch Assembly			☐

SECTION 13

Limited Warranty

Smiths Medical ASD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the Level 1® H-1200 Fast Flow Fluid Warmer, not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and excludes any accessory items or equipment used with the Level 1® H-1200 Fast Flow Fluid Warmer.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any Level 1® H-1200 Fast Flow Fluid Warmer (not including accessories) which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the Level 1® H-1200 Fast Flow Fluid Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases Level 1® H-1200 Fast Flow Fluid Warmer for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370, (800) 258-5361. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE LEVEL 1® H-1200 FAST FLOW FLUID WARMER. If authorized, the Level 1® H-1200 Fast Flow Fluid Warmer must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the Level 1® H-1200 Fast Flow Fluid Warmer has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the Level 1® H-1200 Fast Flow Fluid Warmer serial numbers will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the Level 1® H-1200 Fast Flow Fluid Warmer or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.
2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE LEVEL 1® H-1200 FAST FLOW FLUID WARMER FOR ANY PARTICULAR PURPOSE.
3. The Level 1® H-1200 Fast Flow Fluid Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Level 1® H-1200 Fast Flow Fluid Warmer for any particular medical treatment.
4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the Level 1® H-1200 Fast Flow Fluid Warmer for any particular medical treatment or for any medical complications resulting from the use of the Level 1® H-1200 Fast Flow Fluid Warmer. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Level 1® H-1200 Fast Flow Fluid Warmer.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

SECTION 14

Service

WARNING

No user-serviceable parts. All service must be performed by Smiths Medical or competent personnel.

All service must be performed by Smiths Medical or competent personnel. Service by any other person or organization voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

Non-Warranty Work

Units received which have suffered obvious abuse or impact damage and units no longer under warranty will be promptly inspected and a verbal estimate of repair cost will be supplied. A purchase order will be required from the original purchaser consistent with the verbal estimate. A written estimate will be provided upon request.

Before returning your Level 1® H-1200 Fast Flow Fluid Warmer (Fluid Warmer) or Level 1® H-31, Version B, Air Detector/Clamp for service, contact Smiths Medical for Returned Goods Authorization. Be sure that ALL recirculating solution is drained from the unit before packing the Fluid Warmer for shipment.

Note: *The Fluid Warmer must be cleaned and disinfected for repair shipment or it will be immediately returned as received.*

Additional Documentation

Upon request Smiths Medical will provide the following documentation:

- Circuit diagrams
- Components parts list(s)
- Description of function
- Service and calibration instructions

Disposal Information

Observe national and local codes or requirements for disposal of contaminated materials and for recycling solid waste materials that may impact the environment.

Service Contacts

Contact your Smiths Medical Technical Service Department or Smiths Medical distributor at:

USA/Canada

Smiths Medical ASD, Inc.
1265 Grey Fox Road
St Paul, MN 55112 USA
Tel: 1 800 258 5361 (US/CA)
Tel: + 1 614 210 7300

European Representative

Smiths Medical International Ltd
1500 Eureka Park, Lower Pemberton
Ashford, Kent, TN25 4BF, UK
Tel: +44 (0) 1233 722100

www.smiths-medical.com

SECTION 15

Specifications

System Specifications

Standard Compliance	Guidelines
Product Safety	IEC 60601-1:2005
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class B
Enclosure Protection	IEC 60529 IP Code: IPX1
Fluid Warmers	ASTM F2172-02

Physical	Measurement
Height, Overall	67 inches (1.7 m)
Width, Overall	20 inches (51 cm)
Depth, Overall	20 inches (51 cm)
Weight Assembled; Dry	63 pounds (28.5 kg)
Recirculating Solution Capacity	0.37 gallons (1.4 L)
Air Source Pressure	300 (294 ± 6) mm/Hg

Environmental	Temperature	Humidity [%]
Operation	10°C to 40°C	10 to 95
Transportation	-18°C to 60°C	5 to 95
Storage	5°C to 40°C	5 to 95

Thermal	
Temperature Set Point	41.7°C ± 0.3°C
Over Temperature Set Point	43.9°C ± 0.1°C

Electrical	Type
Protection Against Electrical Shock	Class I Equipment Type BF Equipment
Mode of Operation	Continuous
Type of Current	Alternating
Ingress Protection Rating	IPX1
MAINS Power Input	115 VAC, 50/60 Hz, 12 Amps
MAINS Power Input	230 VAC, 50/60 Hz, 6.3 Amps
Auxiliary MAINS Outlet	115 VAC, 1.5 Amps
Auxiliary MAINS Outlet	230 VAC, 0.75 Amps

Electromagnetic Environment Recommendations

Recommended separation distances between portable and mobile RF communications equipment and the Level 1® H-1200 Fast Flow Fluid Warmer			
The Fluid Warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fluid Warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fluid Warmer as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power or transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d=[3.5/V1]√P	80 MHz to 800 MHz d=[3.5/E1]√P	800 MHz to 2,5 GHz d=[7/E1]√P
0.01	0.116	0.116	0.233
0.1	0.368	0.368	0.737
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.* **Note 2** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*			

Disposable Administration Set Specifications

DI-50	
Filter Size	170 Micron
Priming Volume DI-50	56 ml
System 1200 Normothermic (35 – 41°C) Fluid Delivery Range 10°C Input: 20°C Input:	 40 ml/min. to 300 ml/min. 40 ml/min. to 400 ml/min.
Maximum Flow Rate (crystalloid, 300 mmHg, 14g catheter)	500 ml/min.
D/DI-60HL	
Filter Size	170 Micron
Priming Volume D/DI-60HL	74 ml
System 1200 Normothermic (35 – 41°C) Fluid Delivery Range 10°C Input: 20°C Input:	 75 ml/hour to 530 ml/min. 75 ml/hour to 530 ml/min.
Maximum Flow Rate (crystalloid, 300 mmHg, 8.5 F catheter)	530 ml/min.

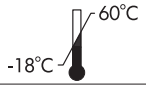
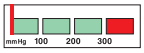
Disposable Administration Set Specifications (continued)

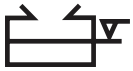
D/DI-70	
Filter Size	170 Micron
Priming Volume D/DI-70	70 ml
System 1200 Normothermic (35 – 41°C) Fluid Delivery Range 10°C Input: 20°C Input:	 50 ml/min. to 500 ml/min. 30 ml/min. to 675 ml/min.
Maximum Flow Rate (crystalloid, 300 mmHg, 8.5 F catheter)	750 ml/min.
D/DI-100	
Filter Size	170 Micron
Priming Volume D/DI-100	65 ml
System 1200 Normothermic (35 – 41°C) Fluid Delivery Range 10°C Input: 20°C Input:	 30 ml/min. to 650 ml/min. 30 ml/min. to 950 ml/min.
Maximum Flow Rate (crystalloid, 300 mmHg, 8.5 F catheter)	950 ml/min.
D/DI-300	
Filter Size	170 Micron
Priming Volume D/DI-300	90 ml
System 1200 Normothermic (35 – 41°C) Fluid Delivery Range 10°C Input: 20°C Input:	 30 ml/min. to 650 ml/min. 30 ml/min. to 1100 ml/min.
Maximum Flow Rate (crystalloid, 300 mmHg, 8.5 F catheter)	1400 ml/min.

SECTION 16

Symbols

Symbol	Meaning
	Type BF Equipment
IPX1	Protected Against Dripping Water
REF	Catalog Number
SN	Serial Number
PN	Part Number
LOT	Batch Code
EC REP	Authorized Representative in the European Community
	Manufacturer
	Date of Manufacture
	Quantity
	Protective Earth [Ground]
	Alternating Current
	Do Not Reuse
	Caution
	Mandatory Action

Symbol	Meaning
	Electrical Shock Hazard
	Not made with natural rubber latex
	Not made with natural rubber latex
	Sterile fluid path, ethylene oxide gas sterilized
	Sterile fluid path, ethylene oxide gas sterilized
	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
CLASS 1	Device is a class type 1 equipment.
	Protective earth terminal
	Refer to Instruction Manual. (The symbol appears on the device with a blue background.)
	Consult instructions for use.
	Do not use if package is damaged.
	Temperature limitation
	Use by
	Recyclable Product
	Pressure Gauge
	Pressurize
	Unpressurize
	Do not bend heat exchanger.

Symbol	Meaning
	Alarm Test
	ON —Only for a part of the equipment. MAINS are connected
	OFF —Only for a part of the equipment. The MAINS are still connected
	Automatic Operation
	Recirculating Solution Temperature
	Over Temperature Test (Recirculating Solution Over Temperature)
	Add Recirculating Solution
	Check Disposables, Check Tubing
	Clamped
	Maximum Reservoir Level
	Minimum Reservoir Level
	**Device has been tested by TÜV SÜD America, a nationally recognized technical laboratory, to meet all requirements for safety.**
	Device has been tested by National Technical Systems, a nationally recognized technical lab, to meet U.S. requirements for safety.
	CE Mark and Notified Body number (0473 indicates AMTAC)
	Humidity Limitation
	Collect separately for electrical and electronic equipment.
	**Contains or Presence of Phthalate: bis(2-ethylhexyl) phthalate (DEHP)**

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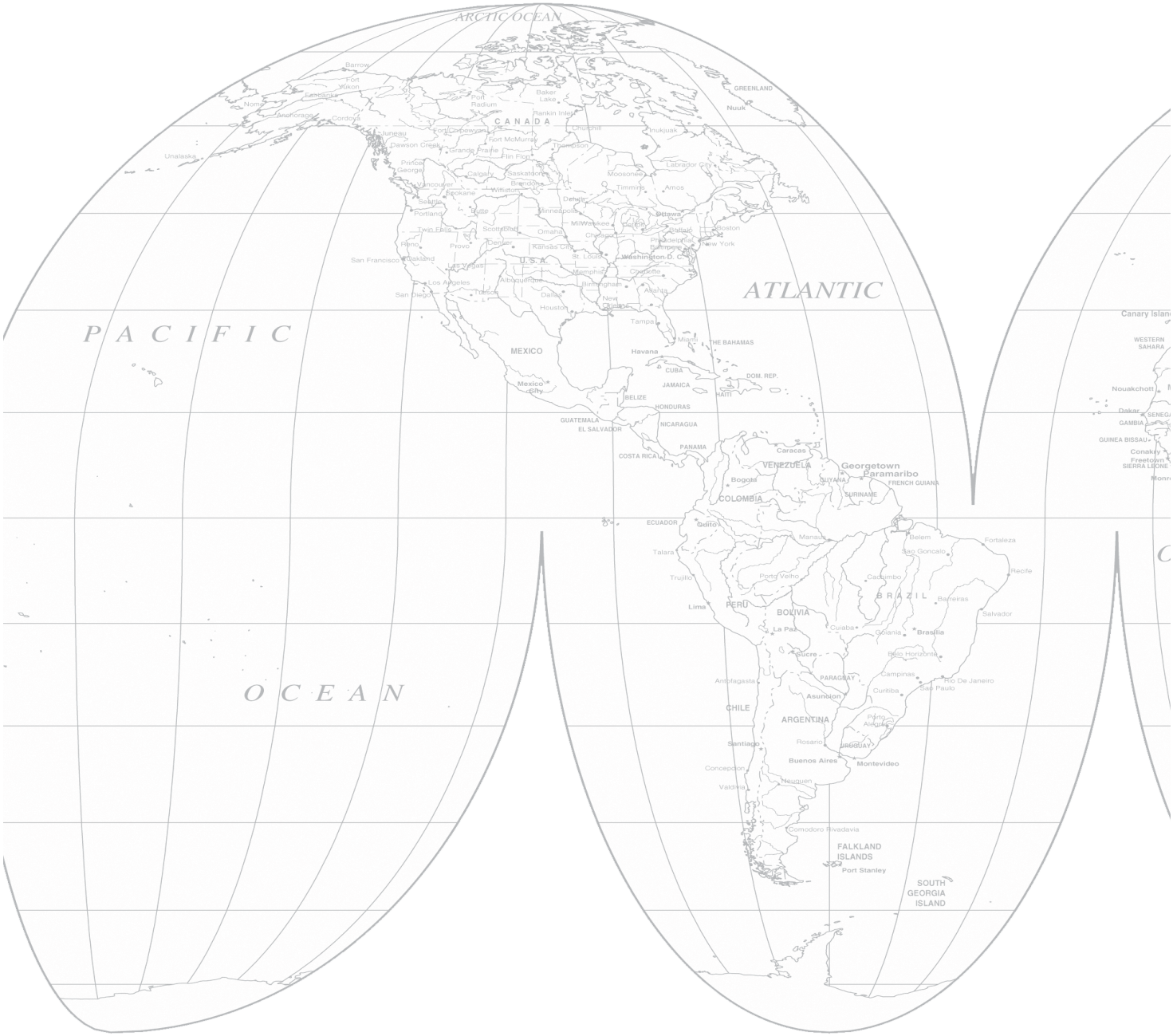

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